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Fig 1

A

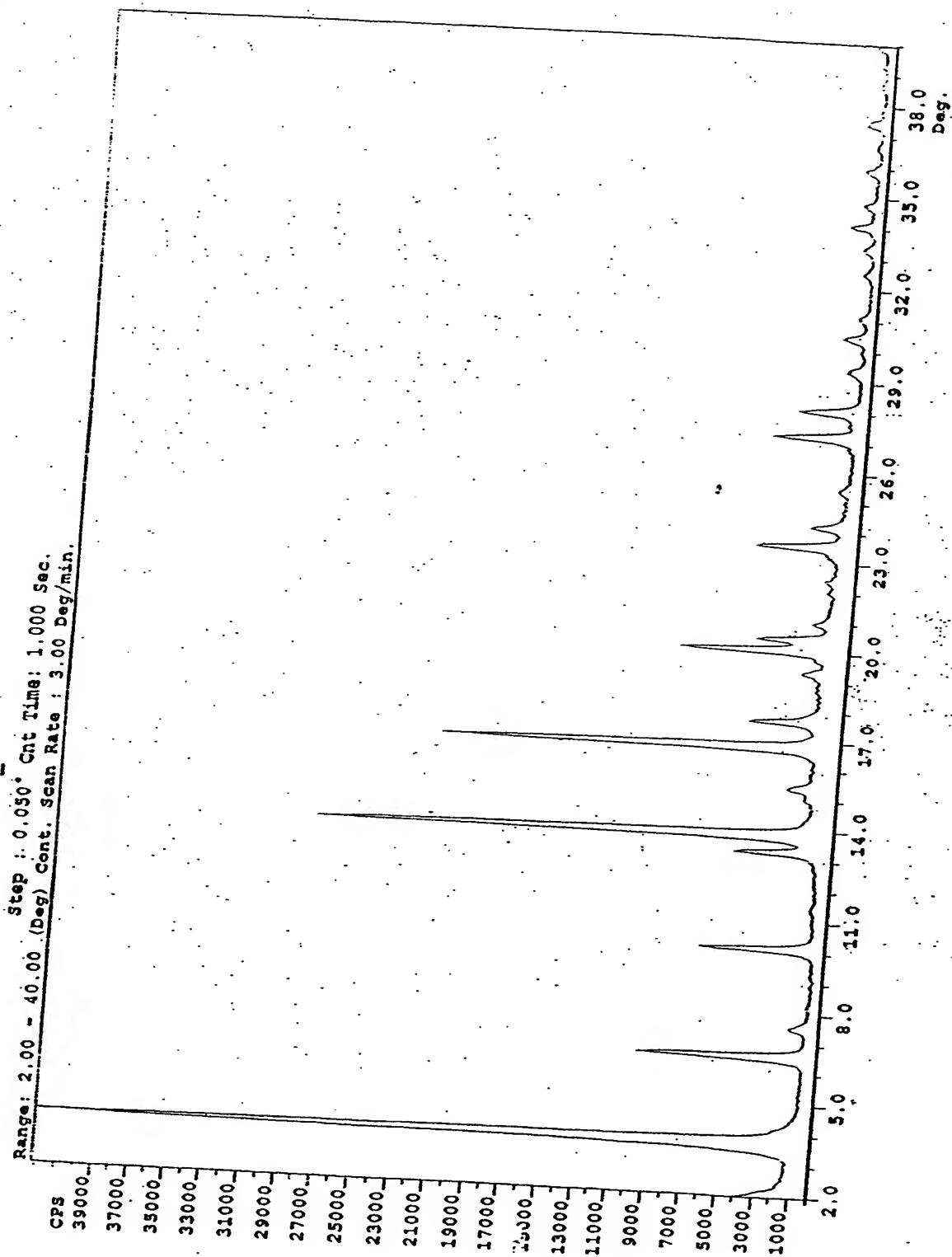


FIG. 2 C

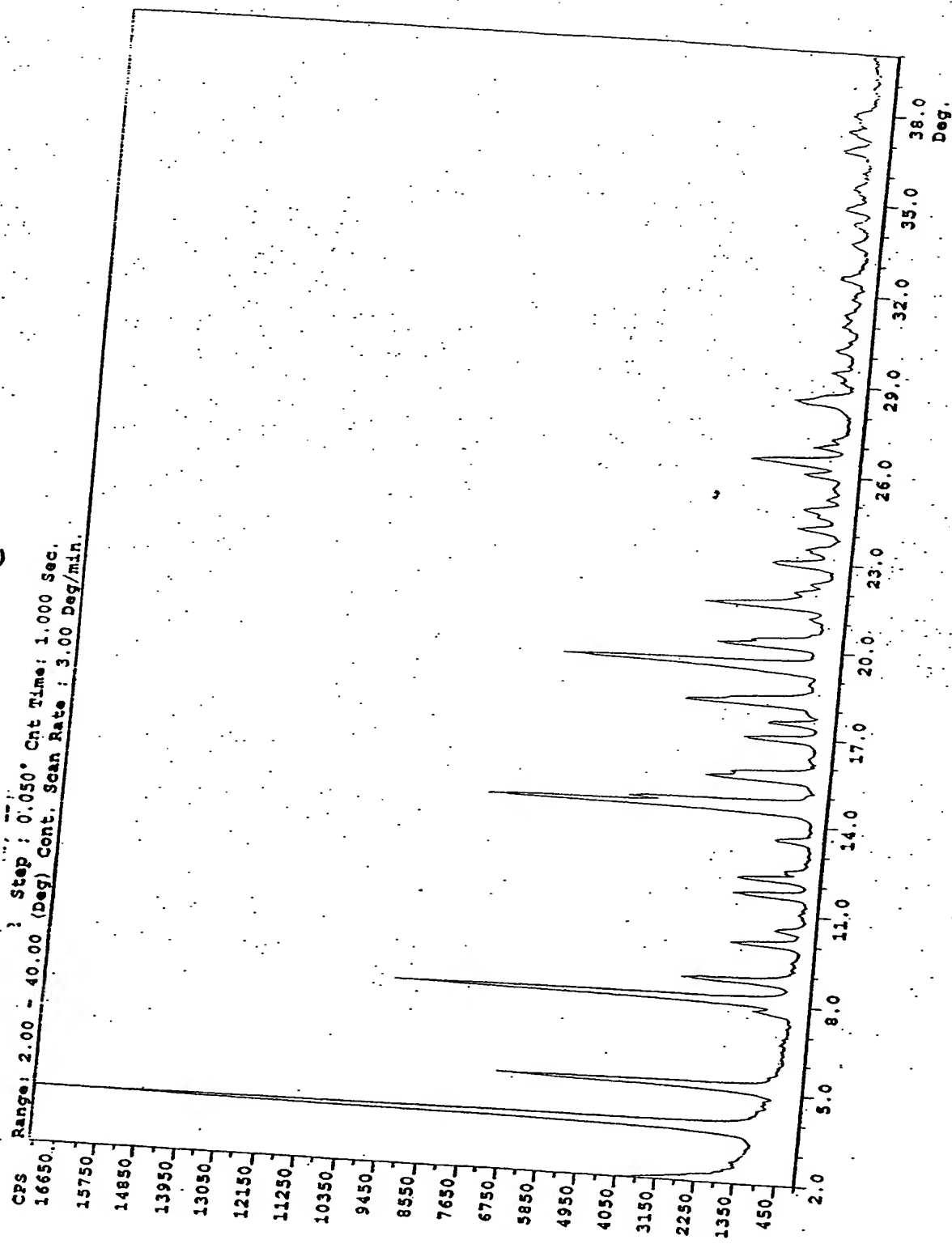


Fig 3 D

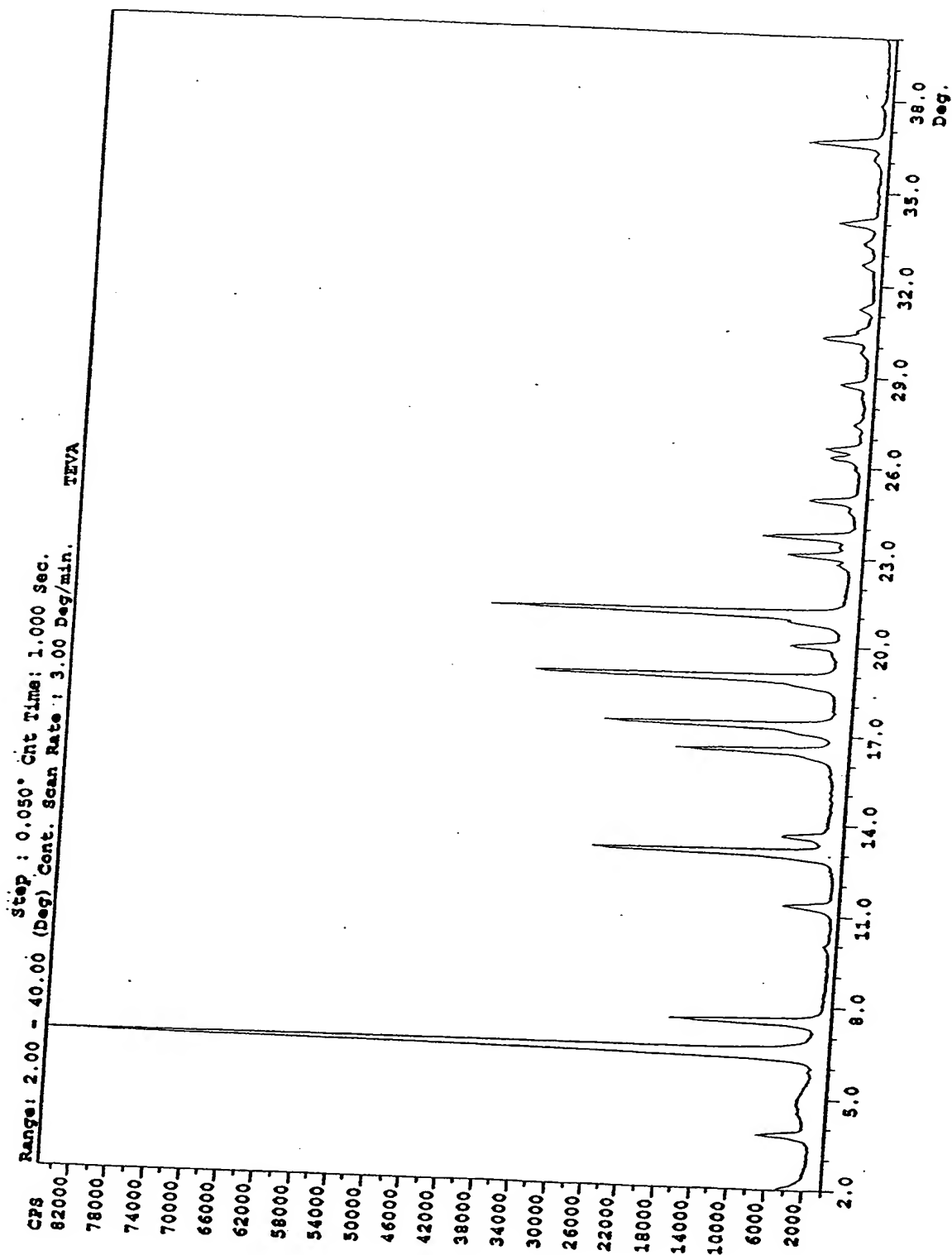


Fig 4 .E

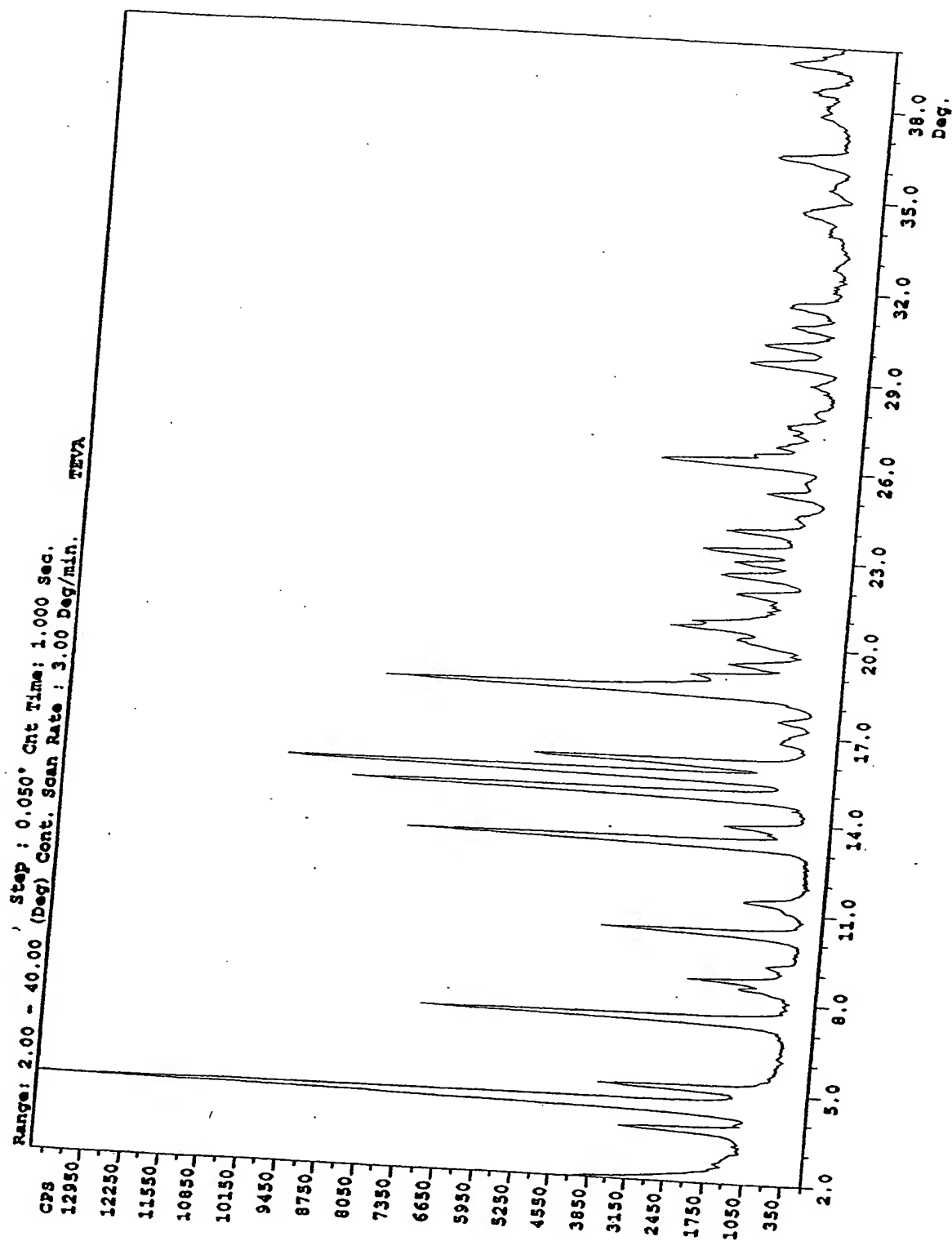


Fig. 5

F

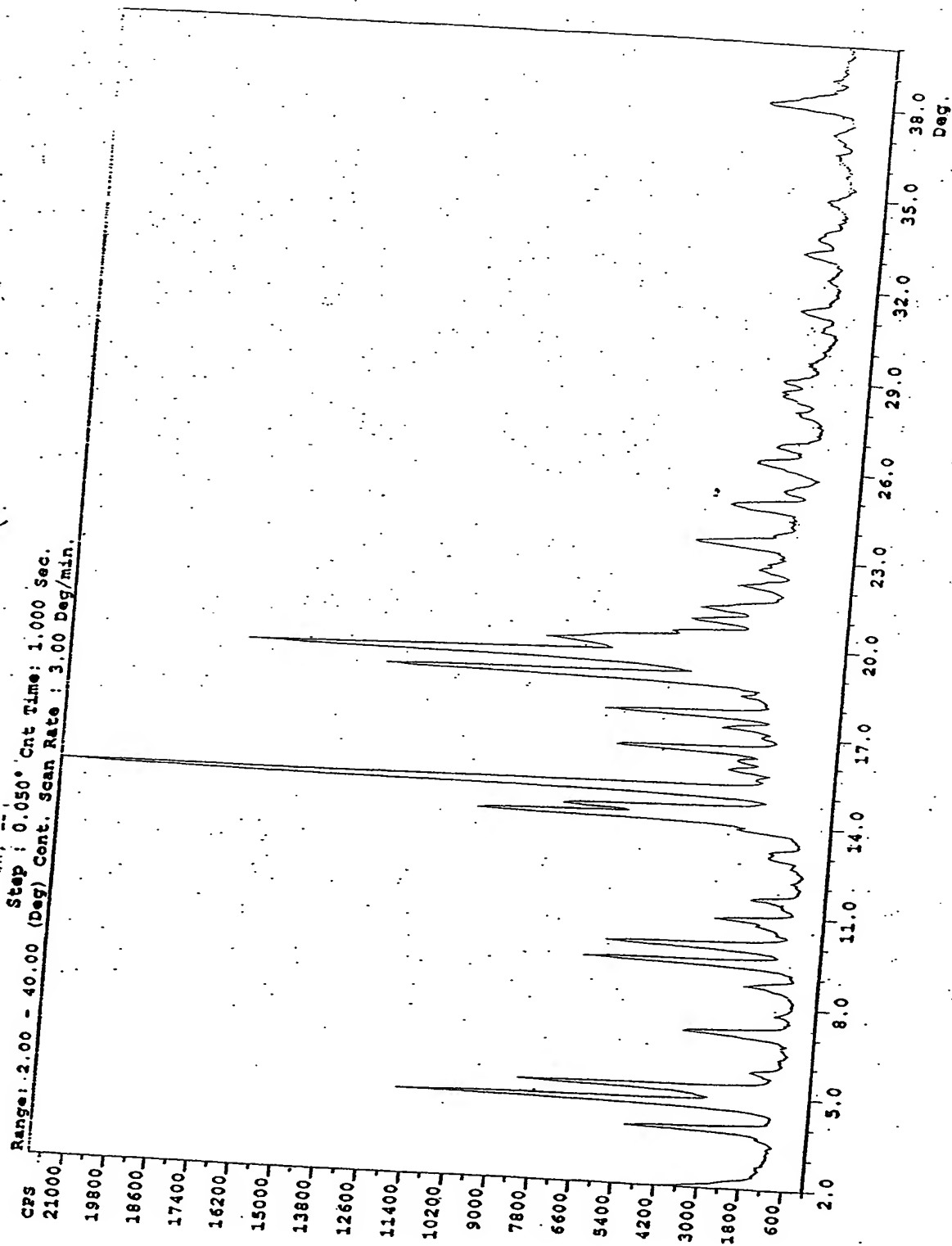


Fig. 6

G

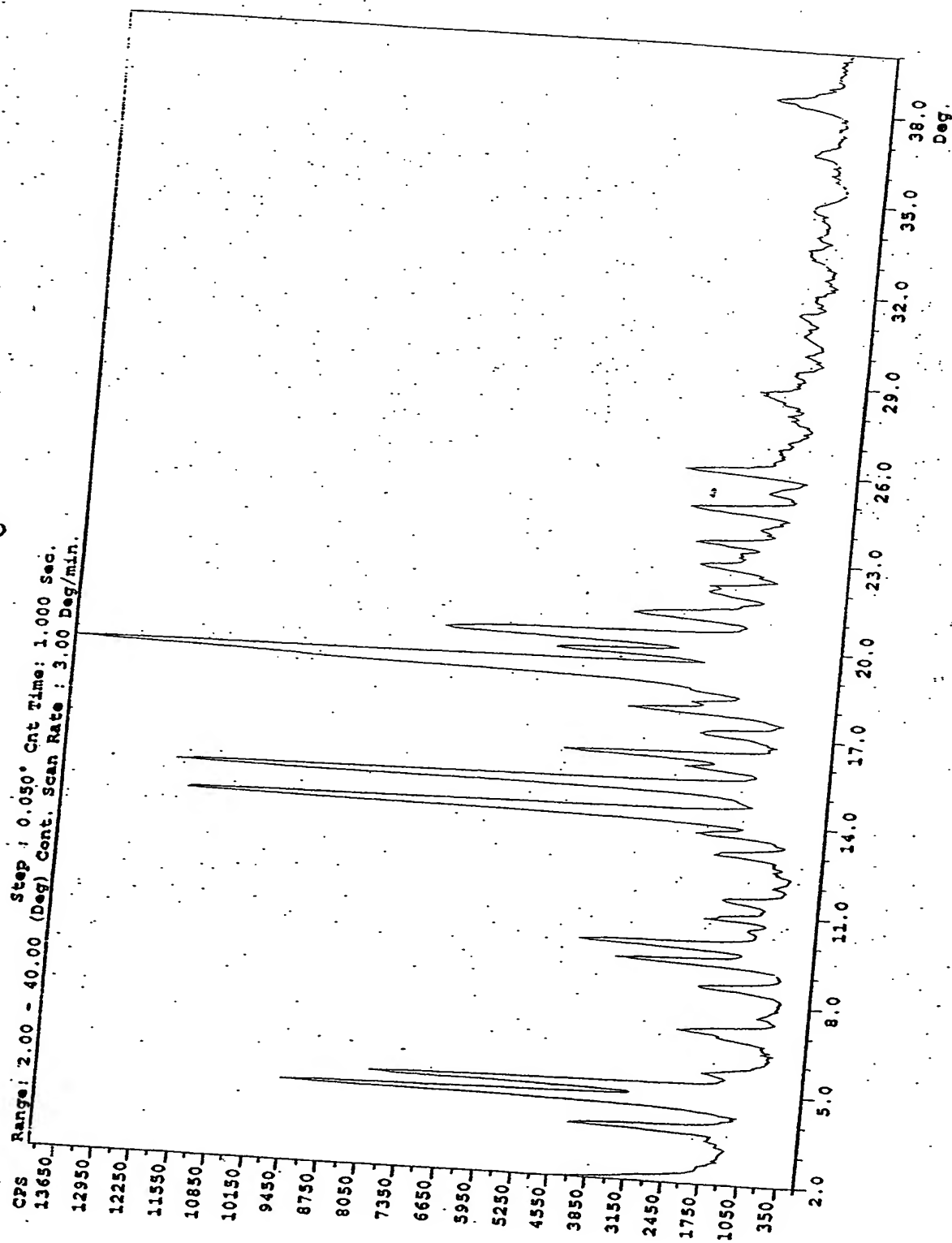


Fig 7 I

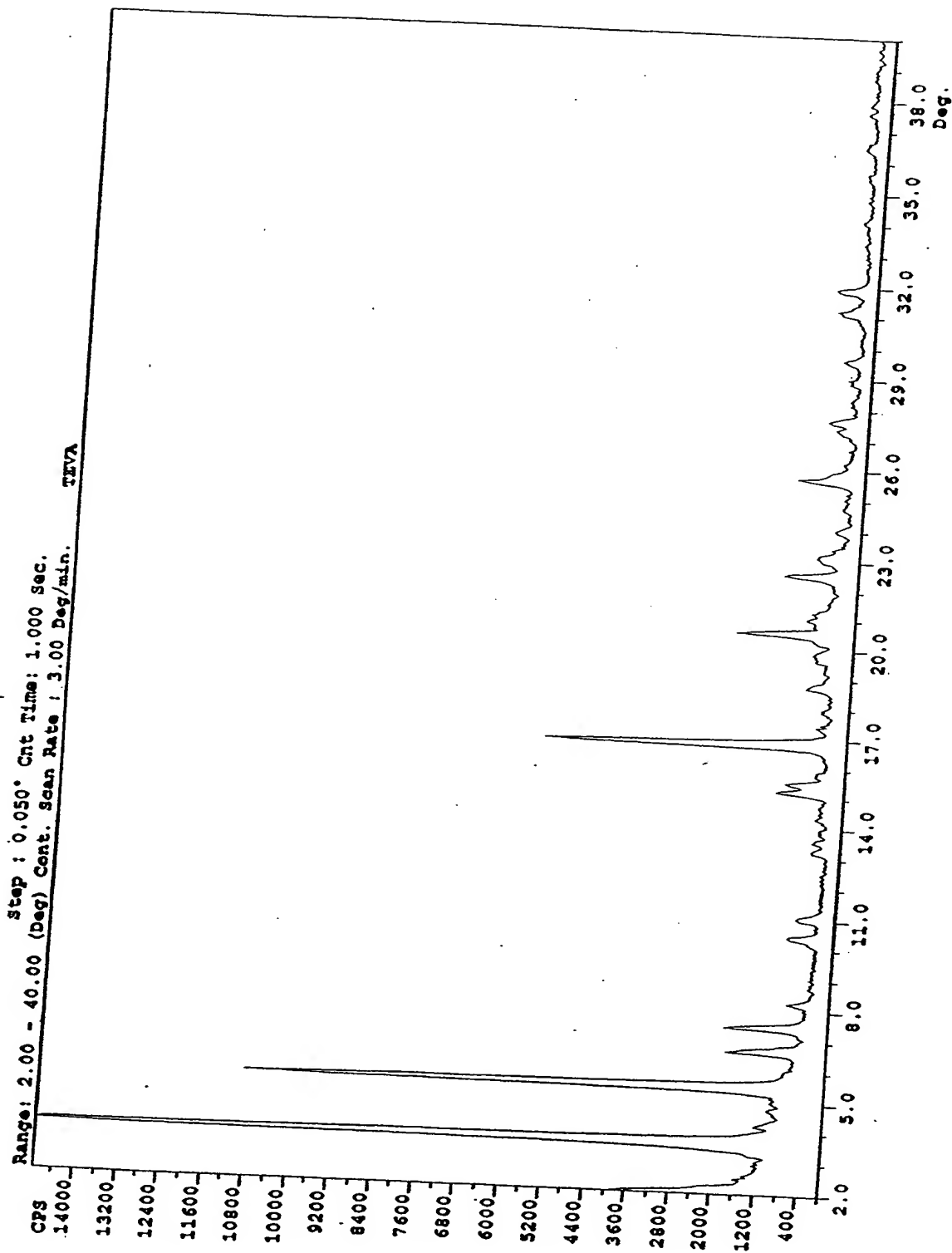


Fig. 8

Range: 2.00 - 40.00 Step: 0.050° Cnt Time: 1.000 Sec.
(Deg) Cnt. Scan Rate: 3.00 Deg/min.

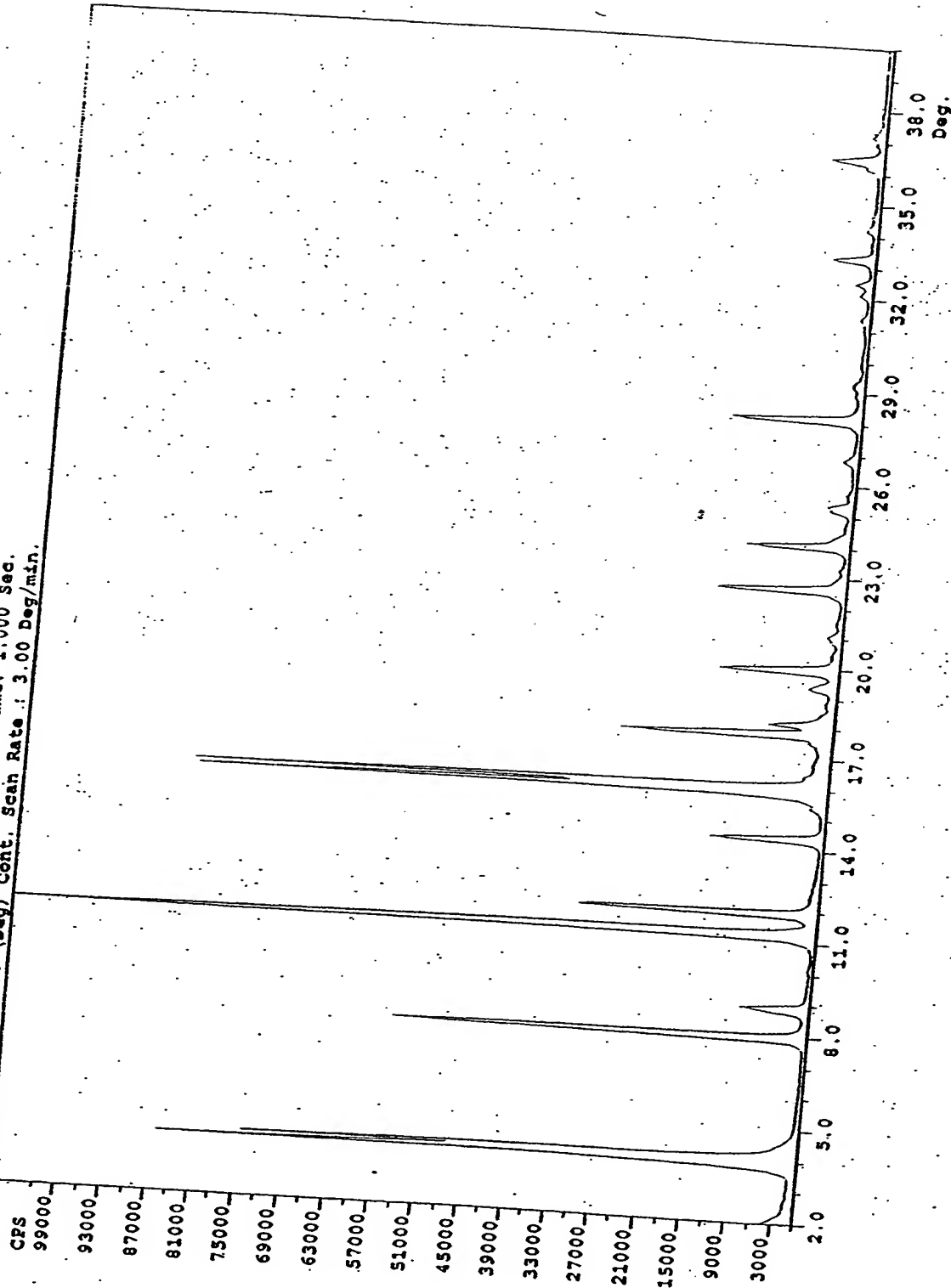


Fig. 9

K

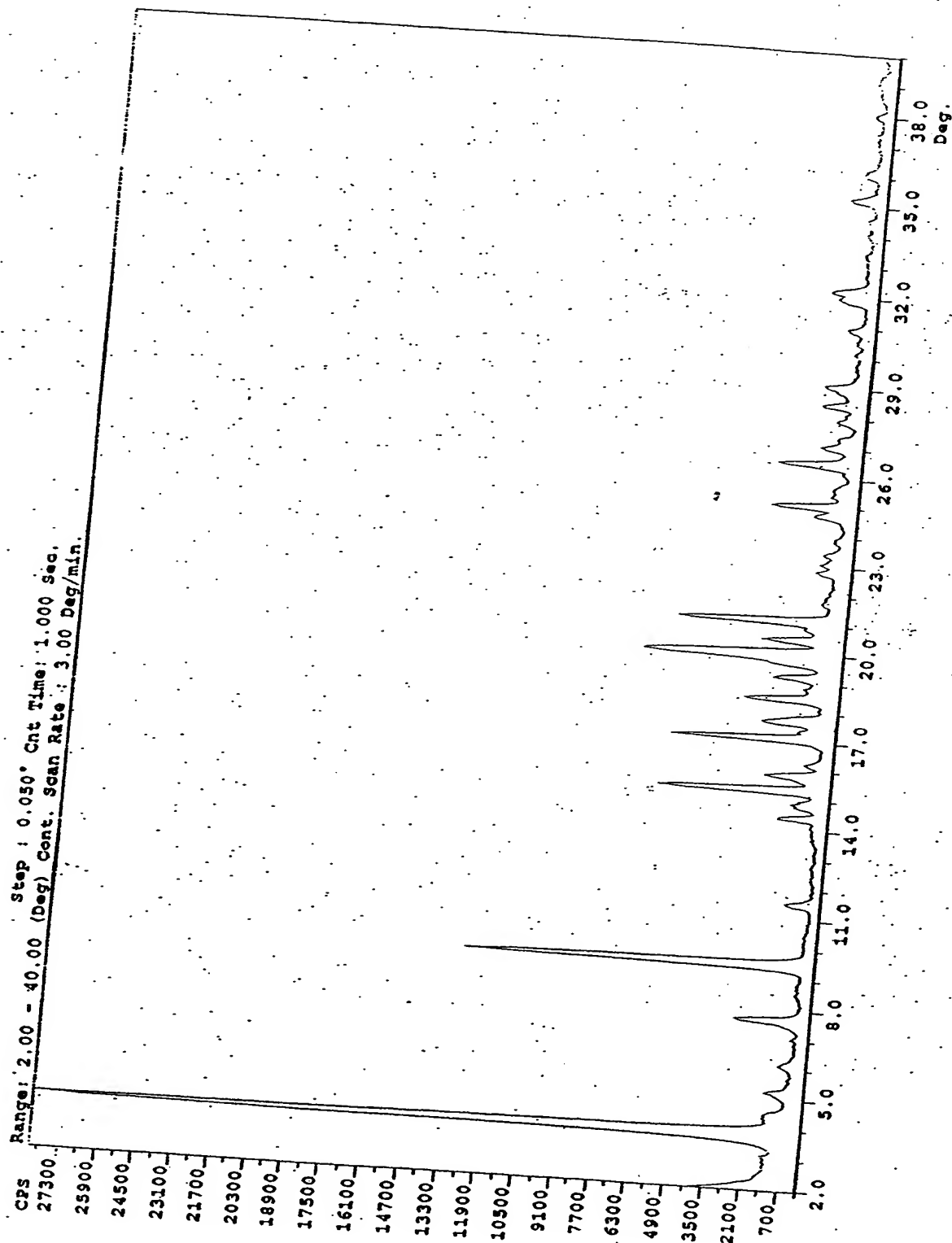


Fig. 10 L

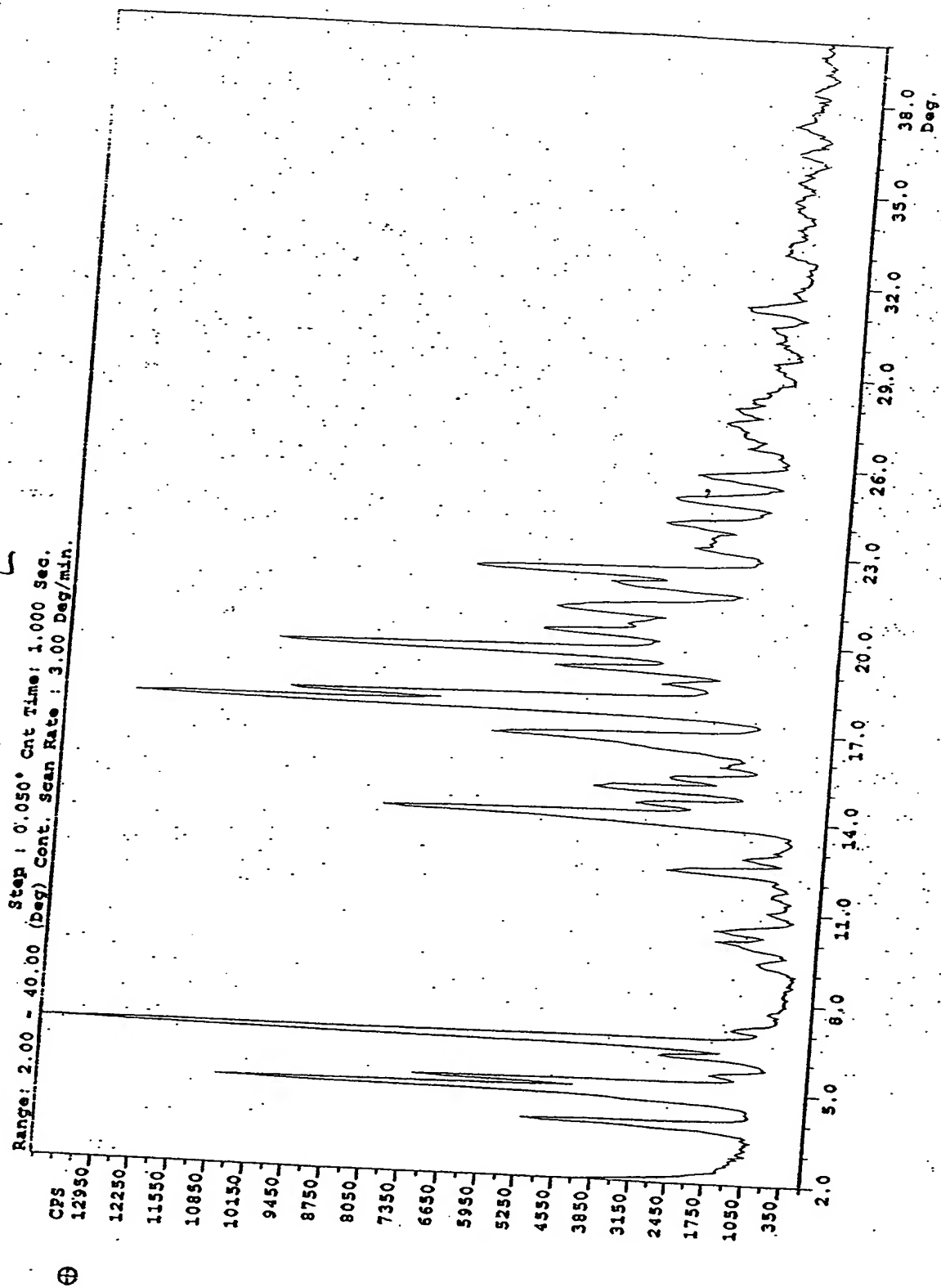


Fig. 11

M

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.
Step: 0.050 (Deg) Cont. Scan Rate: 3.00 Deg/min.

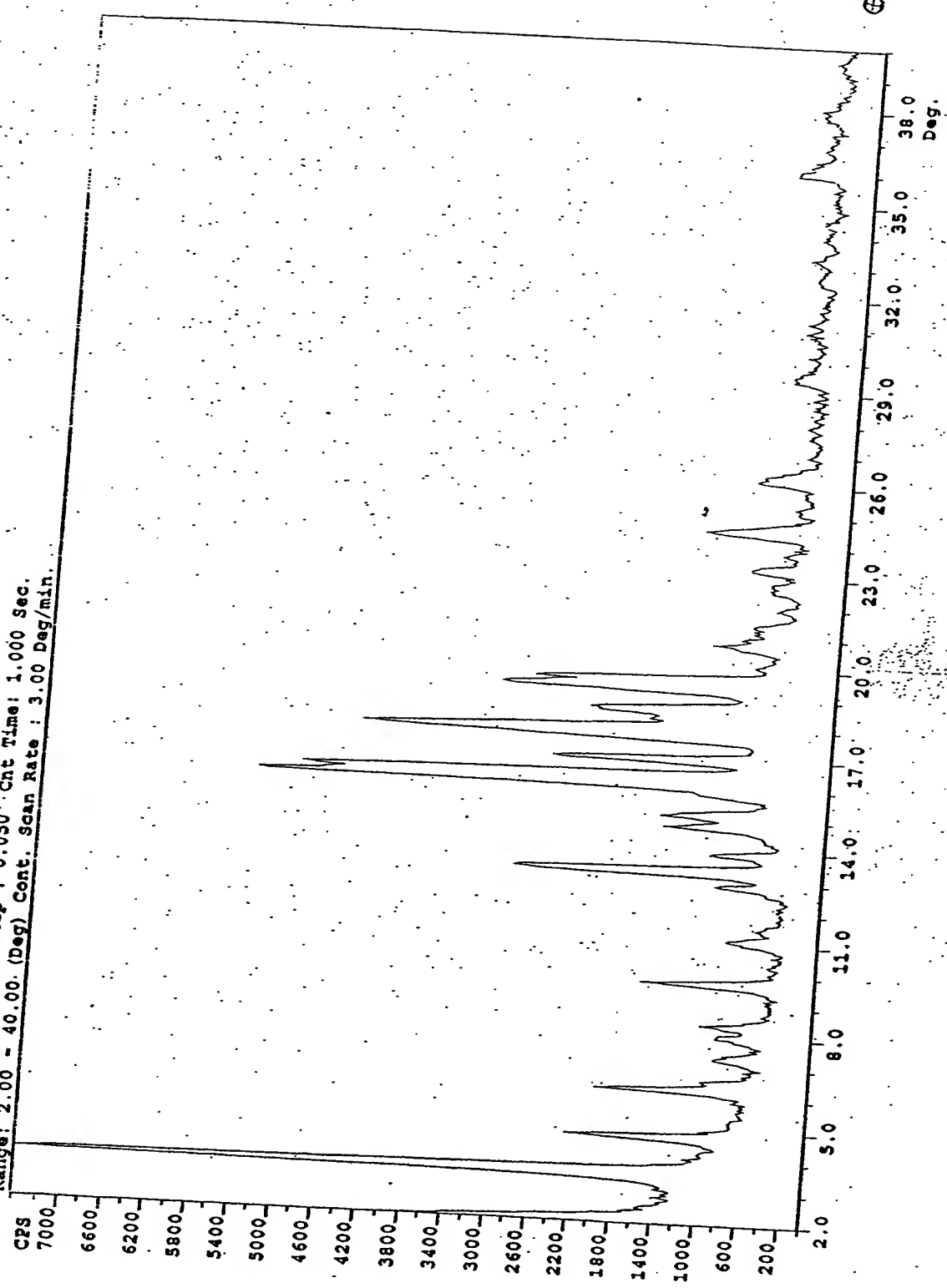


Fig. 12

N

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.
Step: 0.050 (Deg) Cont. Scan Rate: 3.00 Deg/min.

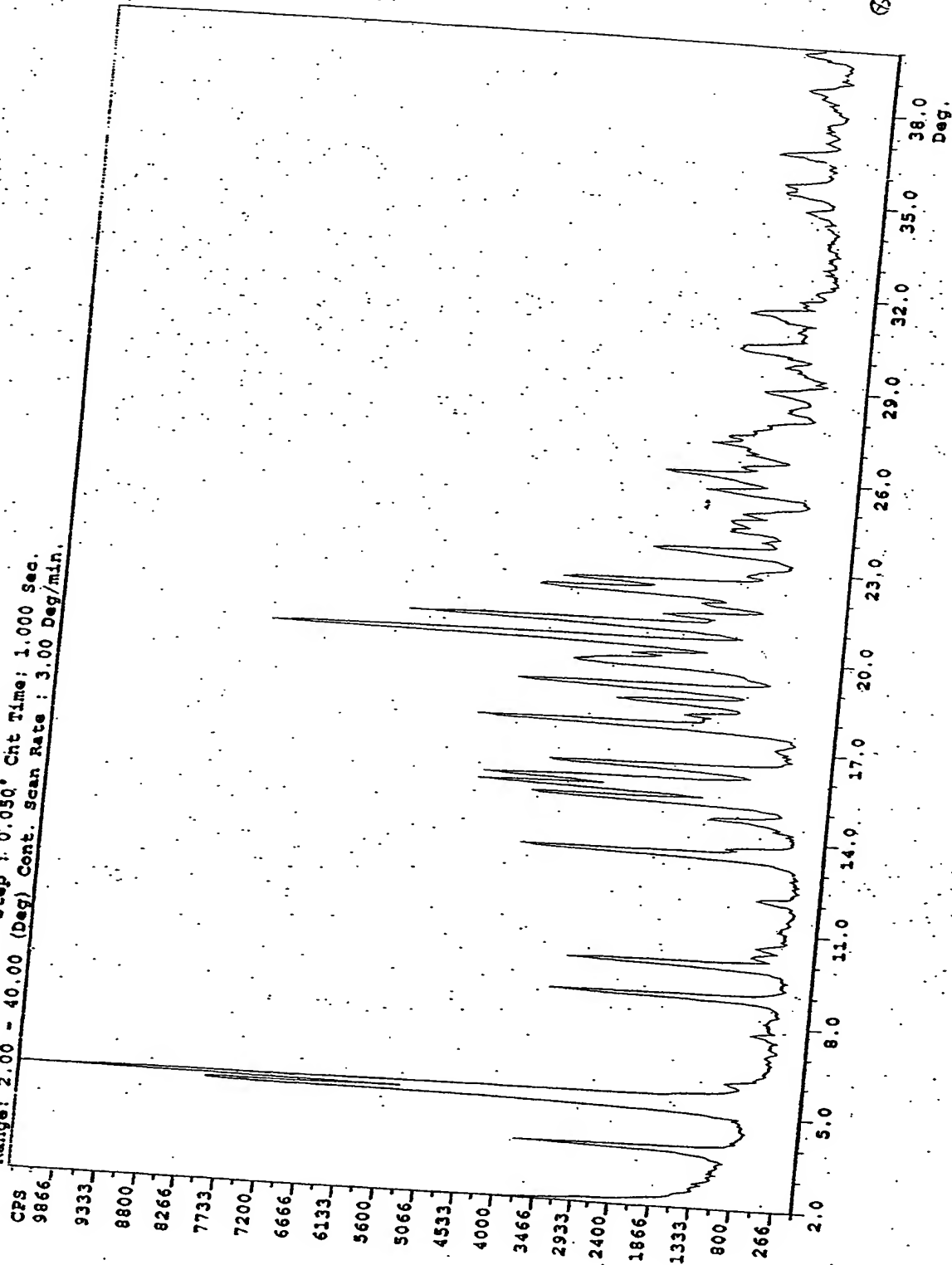


Fig. 13 0

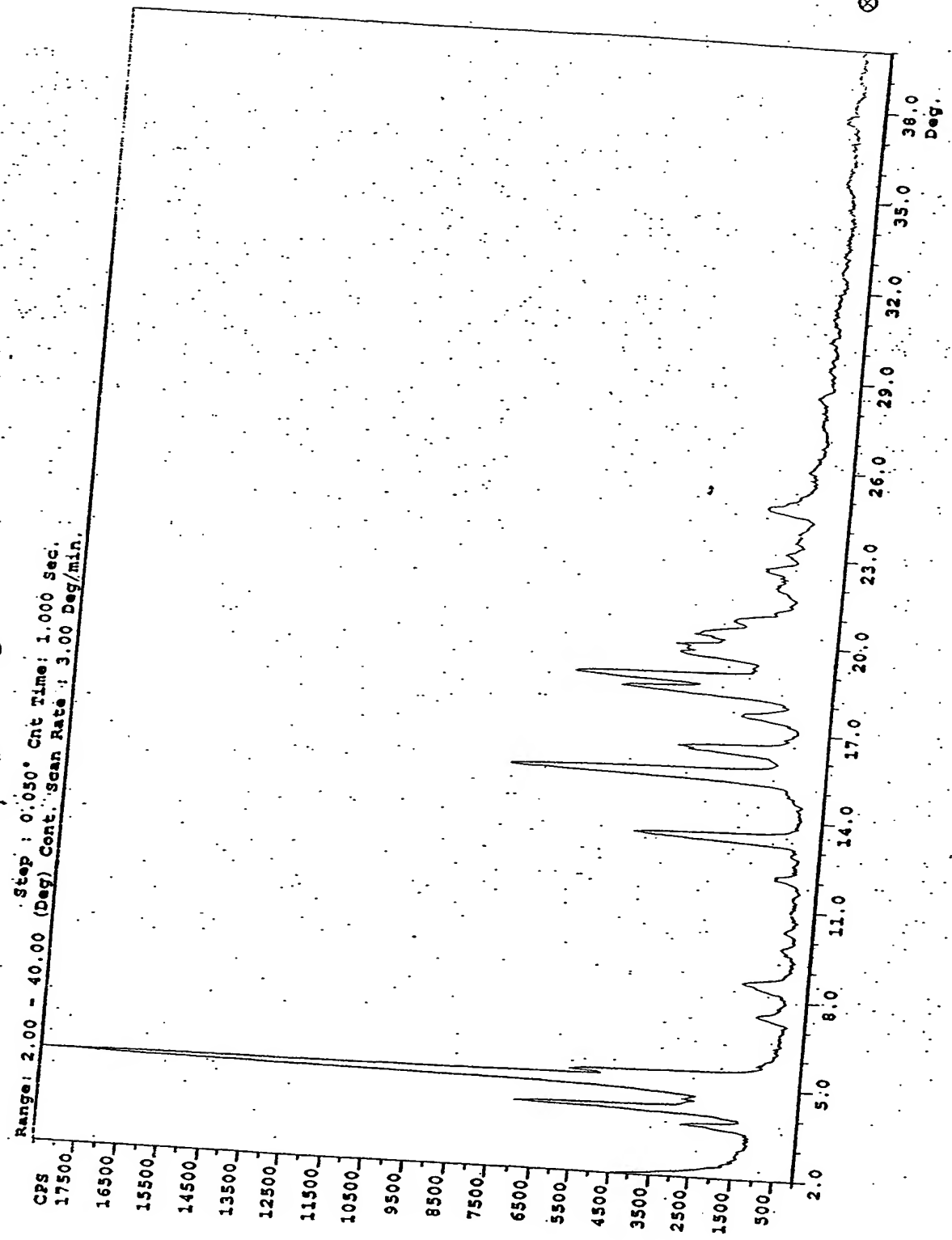


fig. 14

P

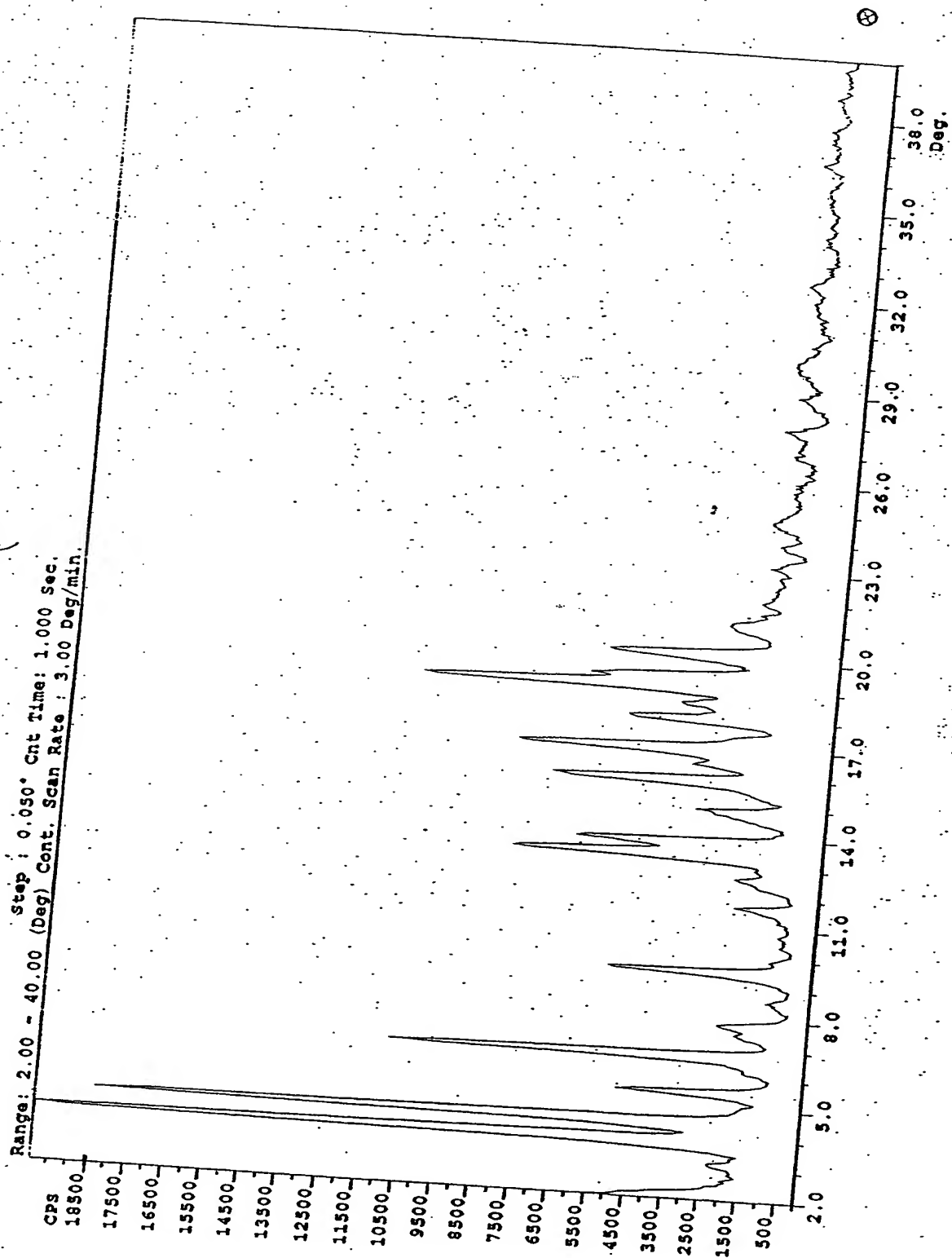


Fig. 15 Q

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.
Step: 0.050 (Deg) Cnt. Scan Rate: 3.00 Deg/min.

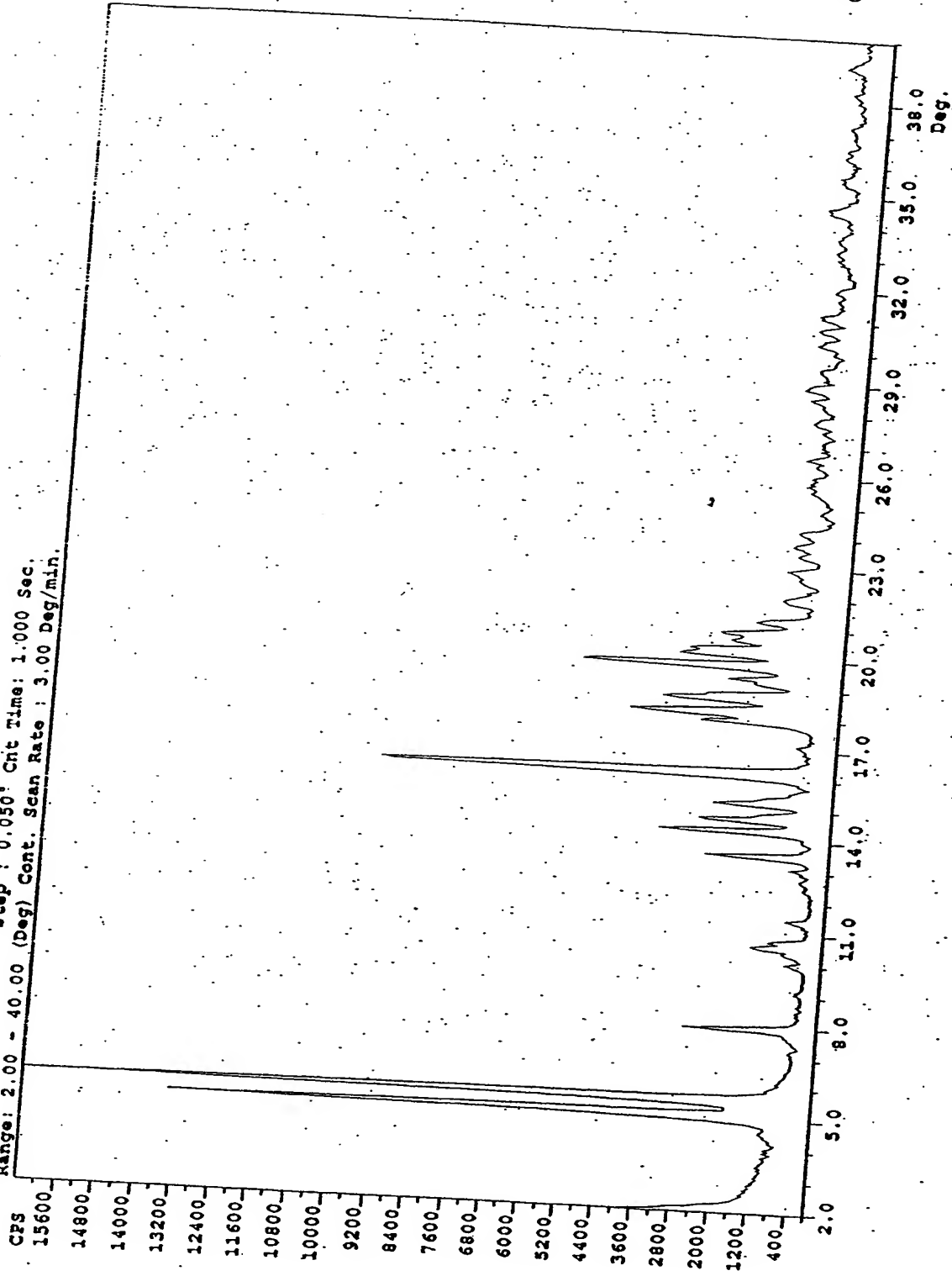


Fig. 16

T

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.
Scan Rate: 3.00 Deg/min.

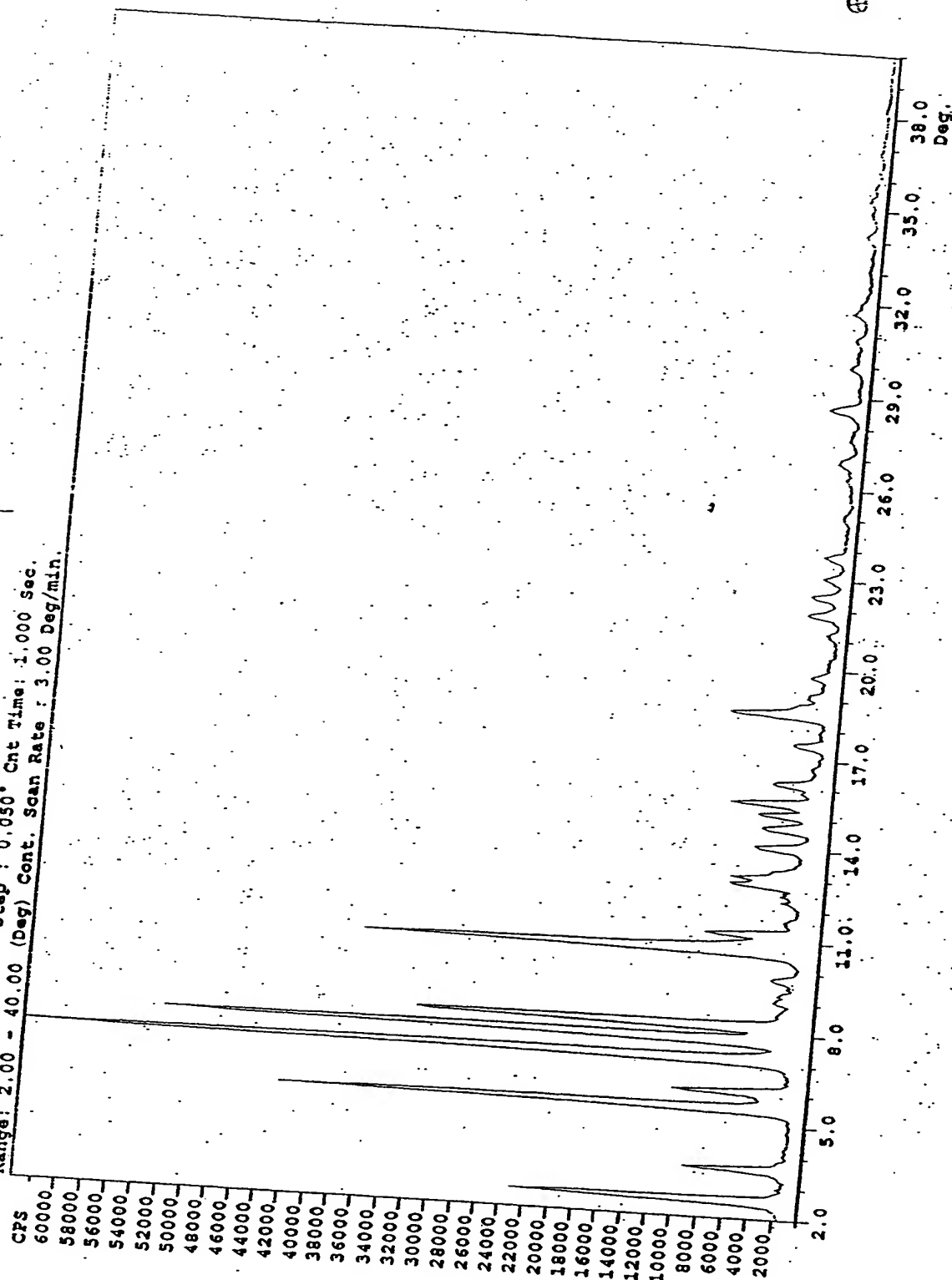


Fig. 17 u

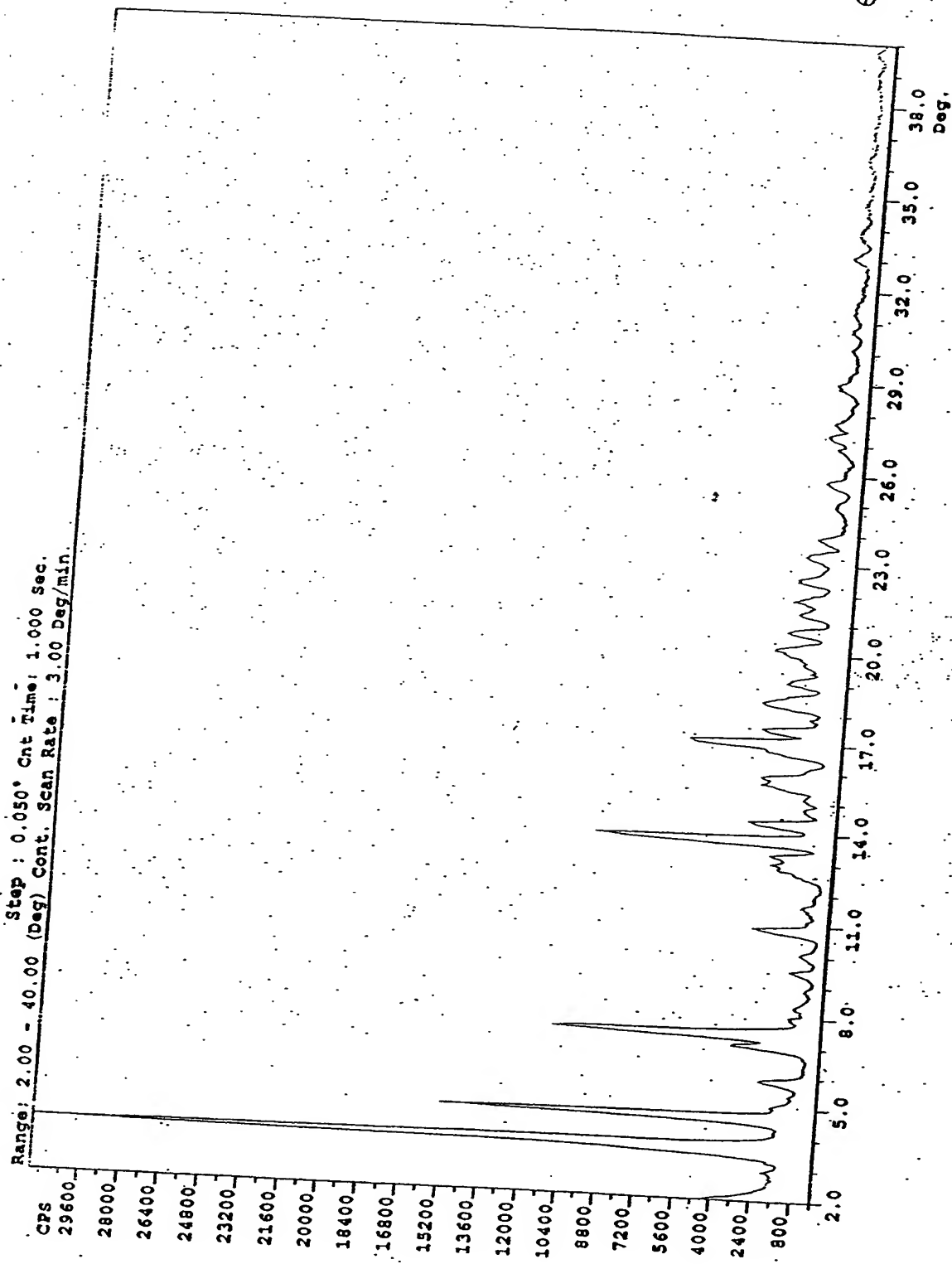


Fig. 18

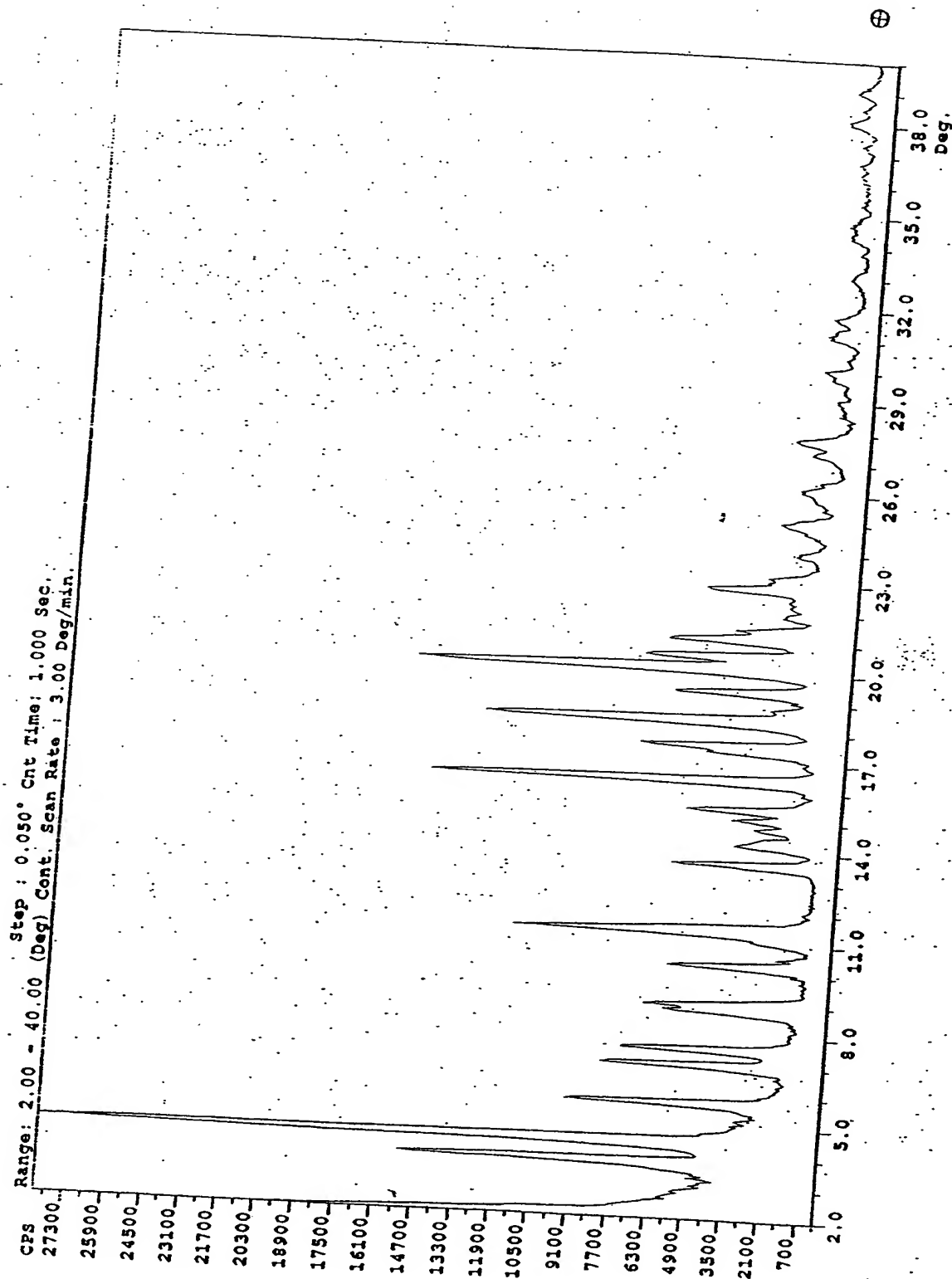


Fig 19 γ

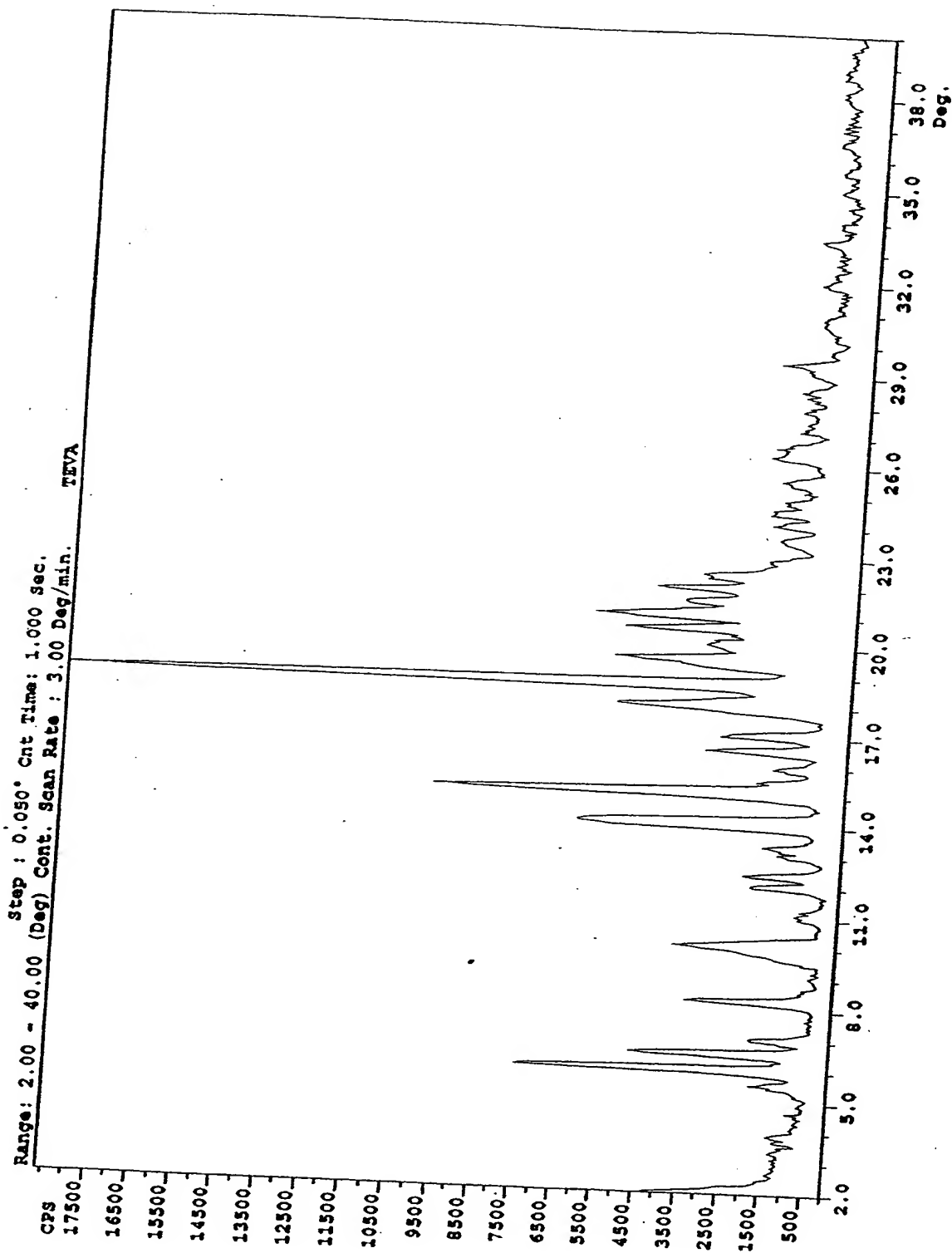


Figure 20 - Nateglinide Form Z

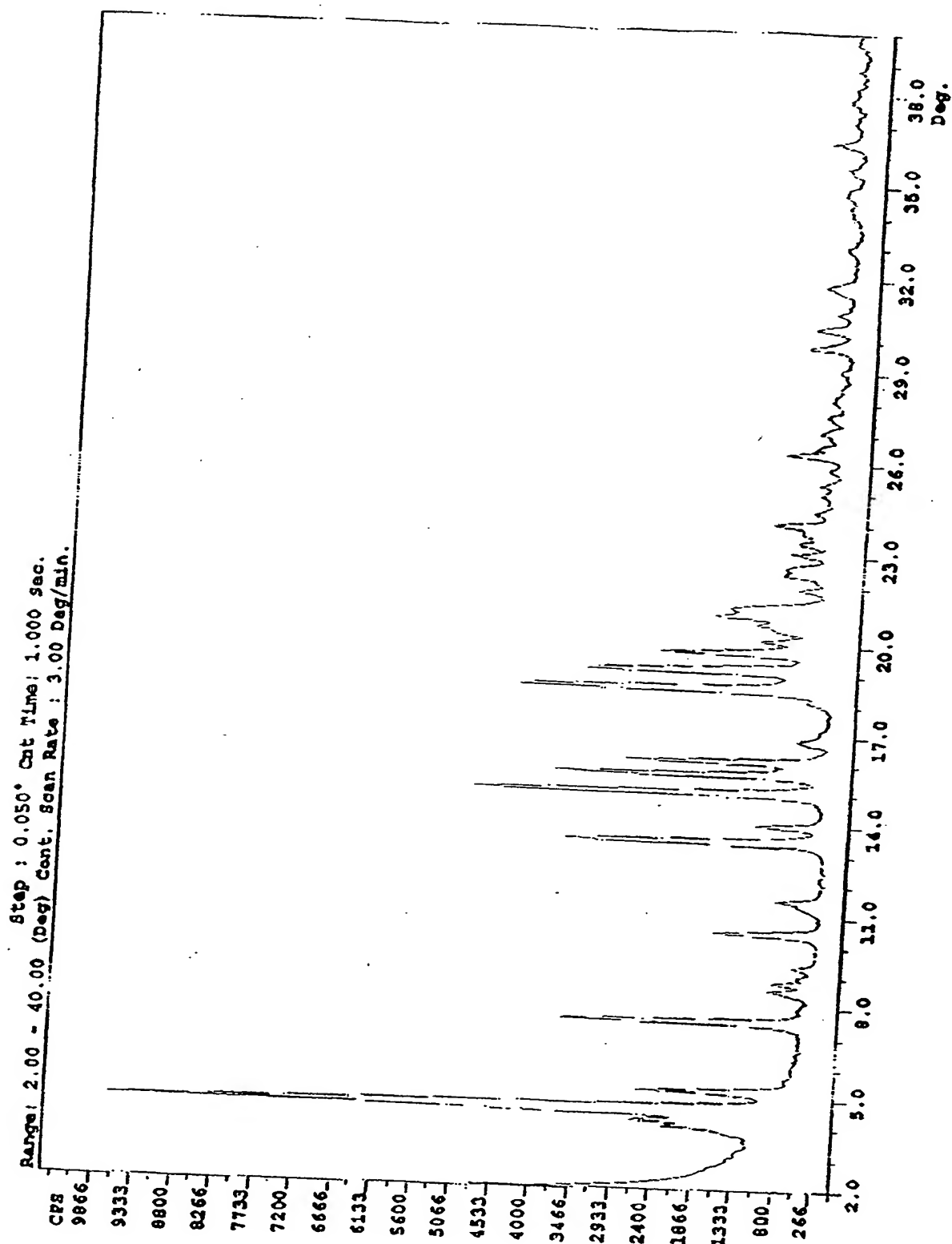


fig 2p x

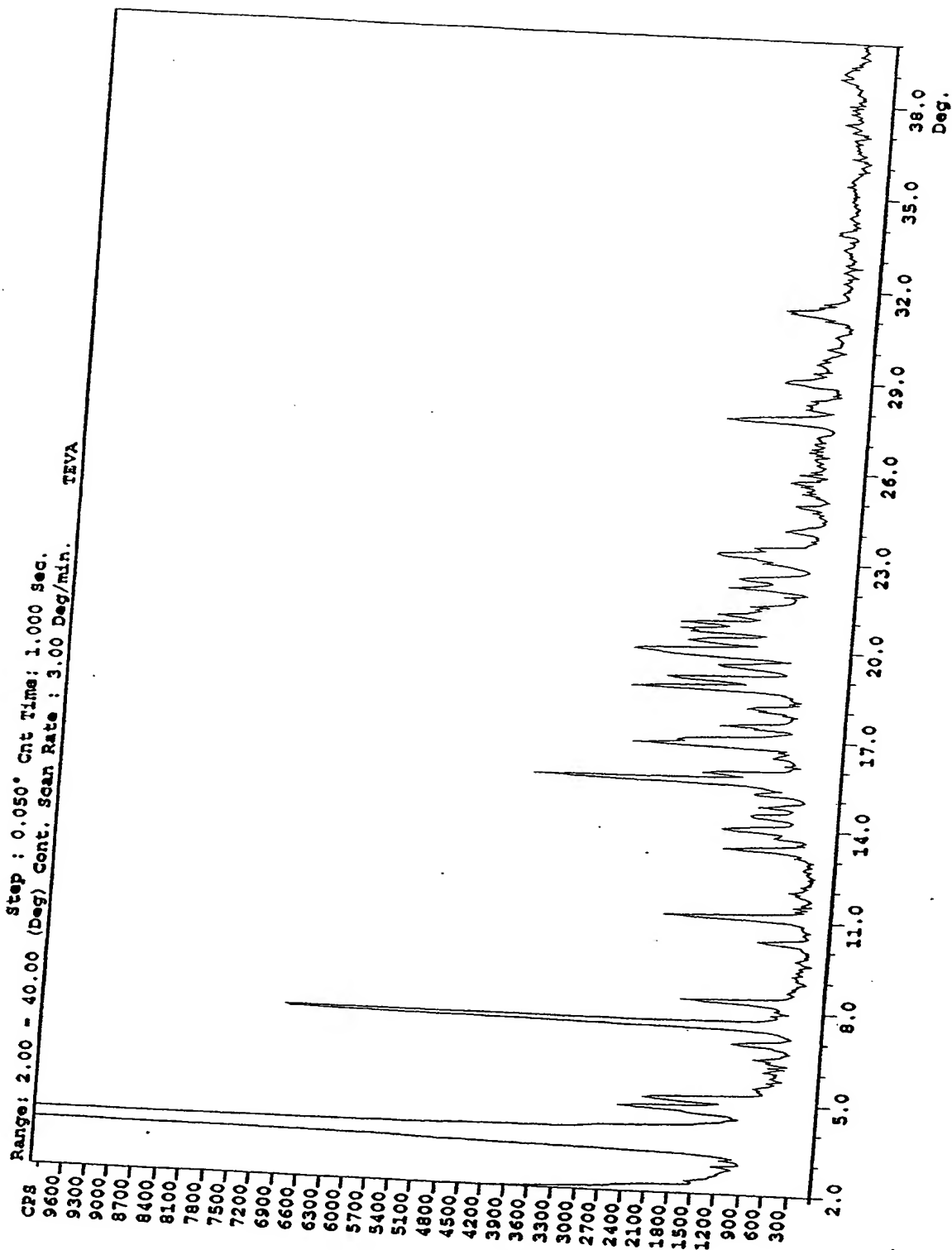


Fig. 2A B

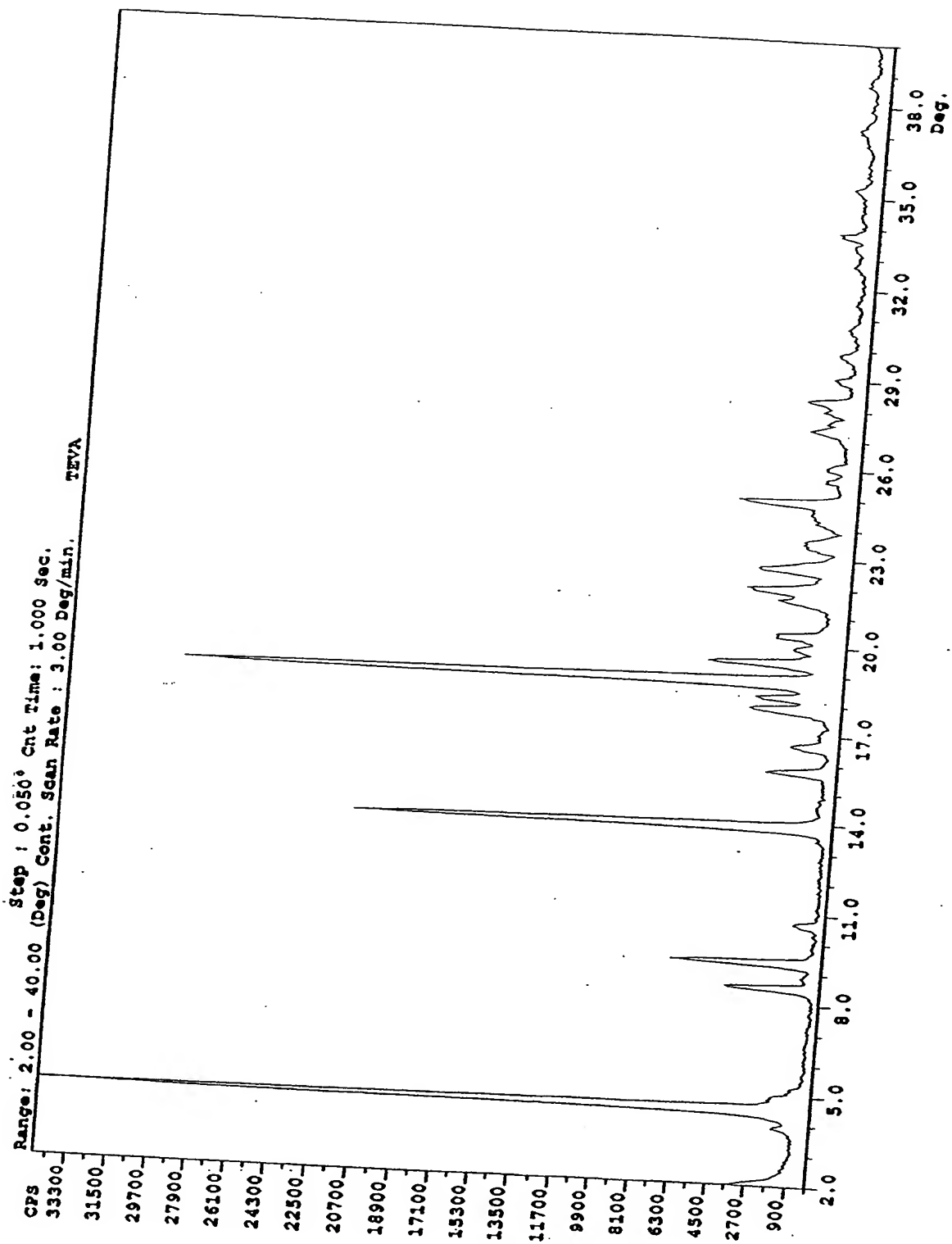


Fig 23 10

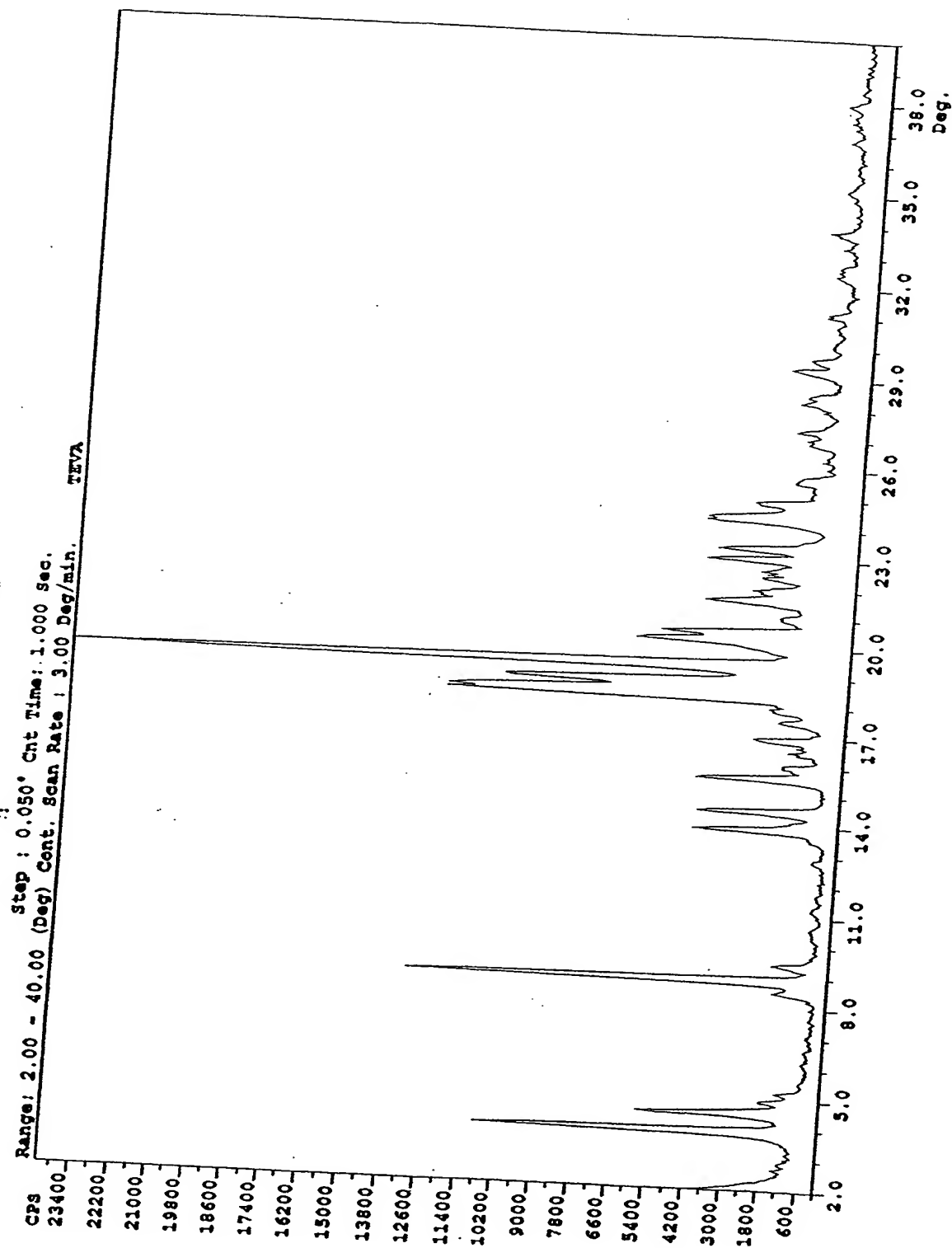


Fig 24

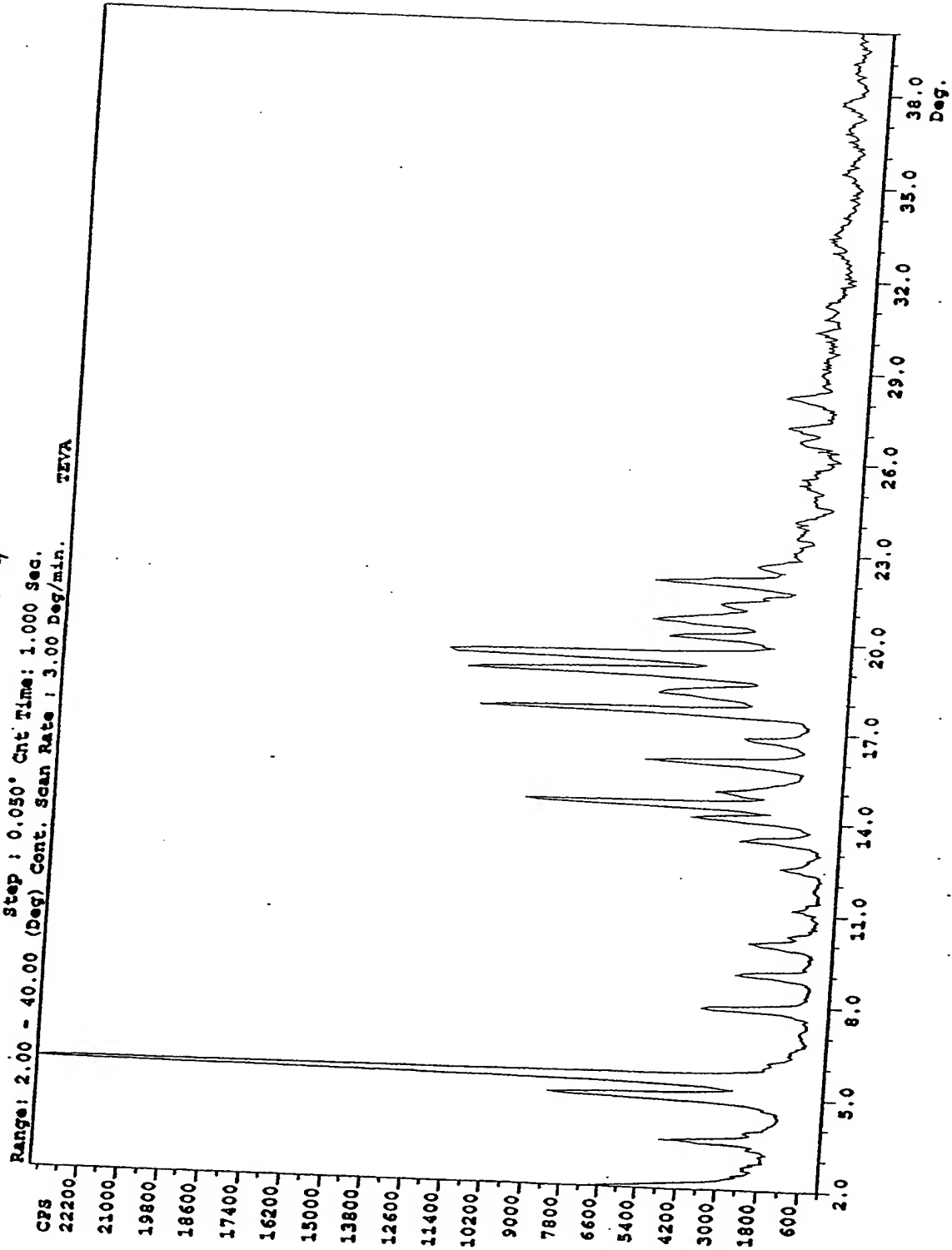


Fig 25

E

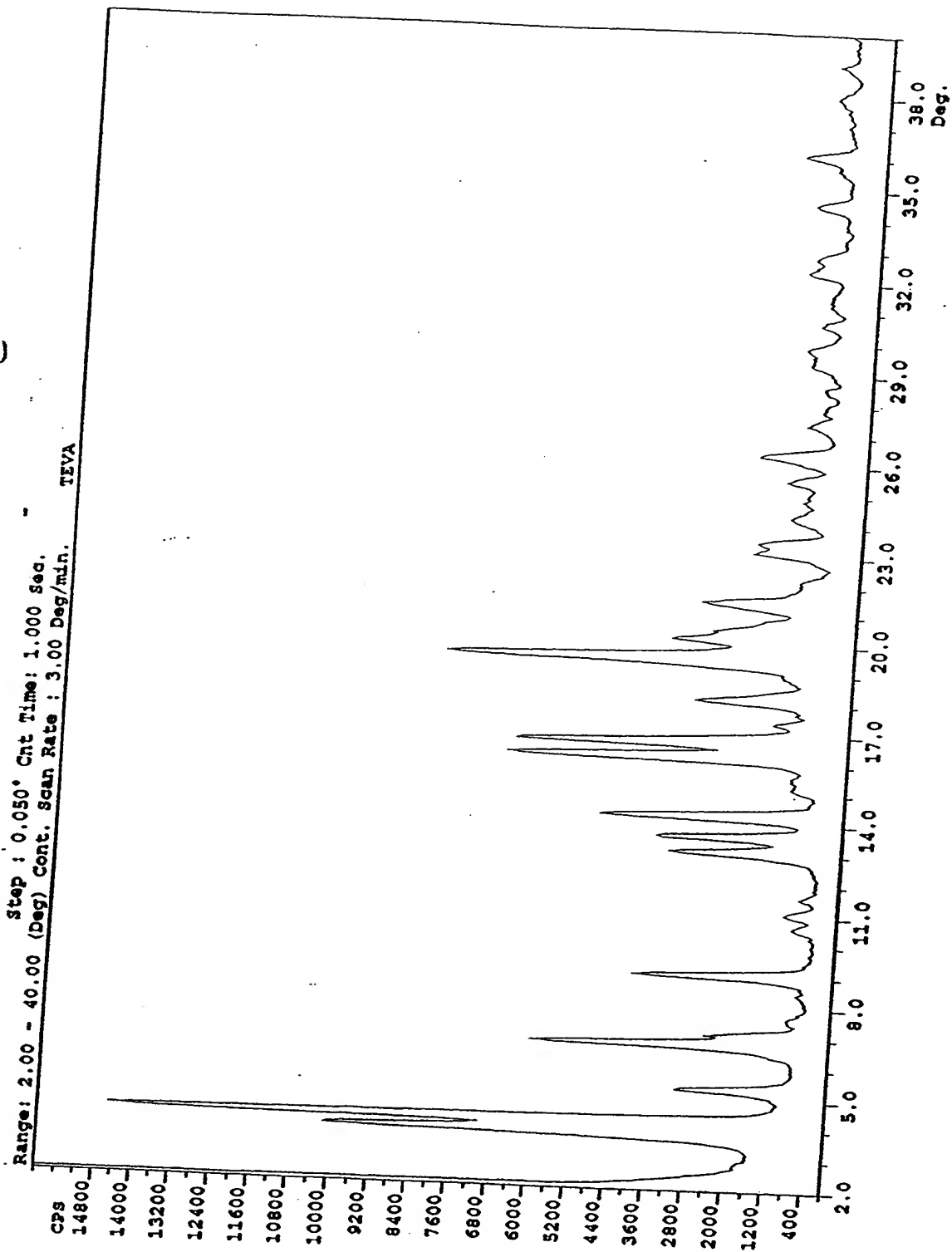
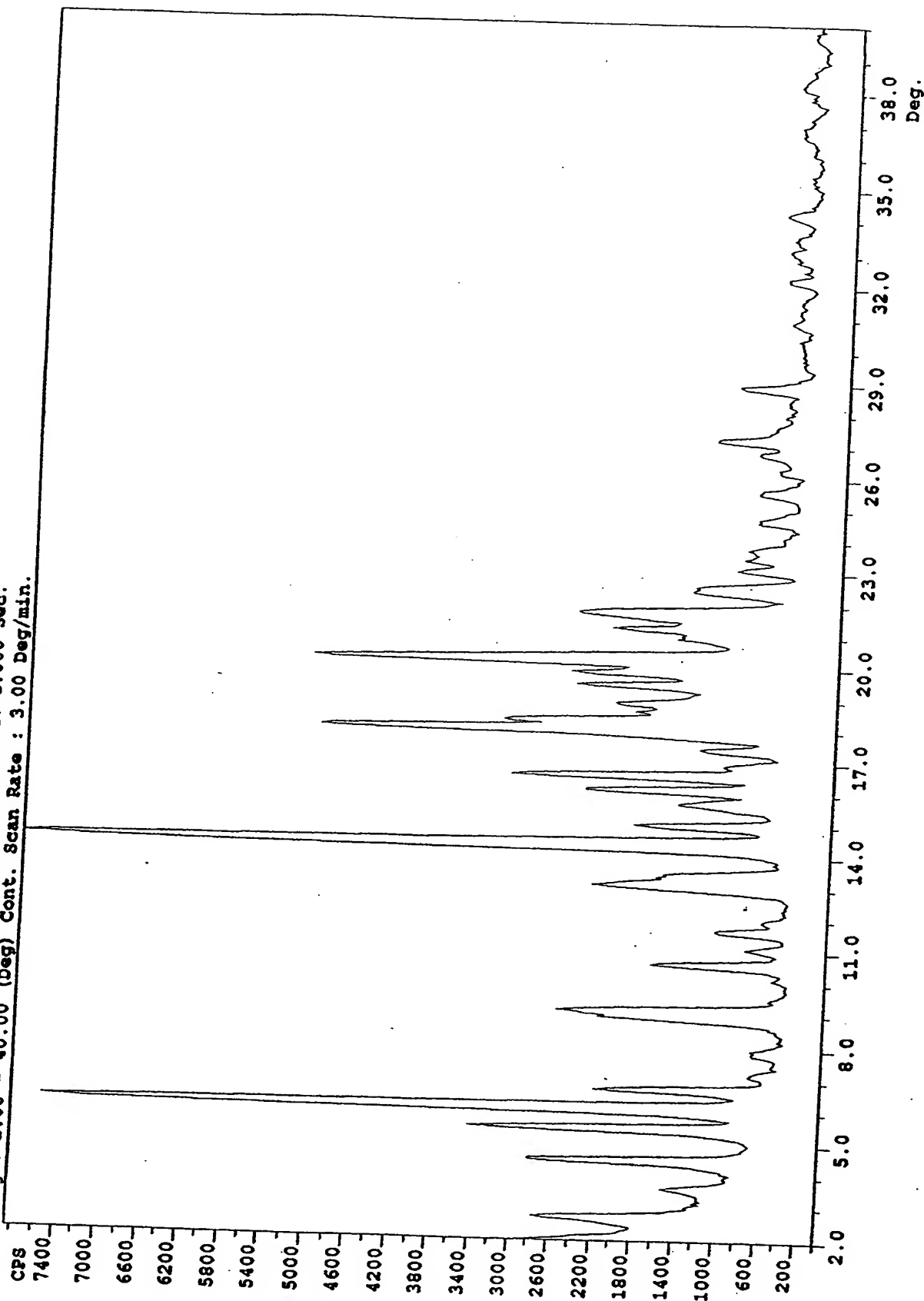


FIGURE 26

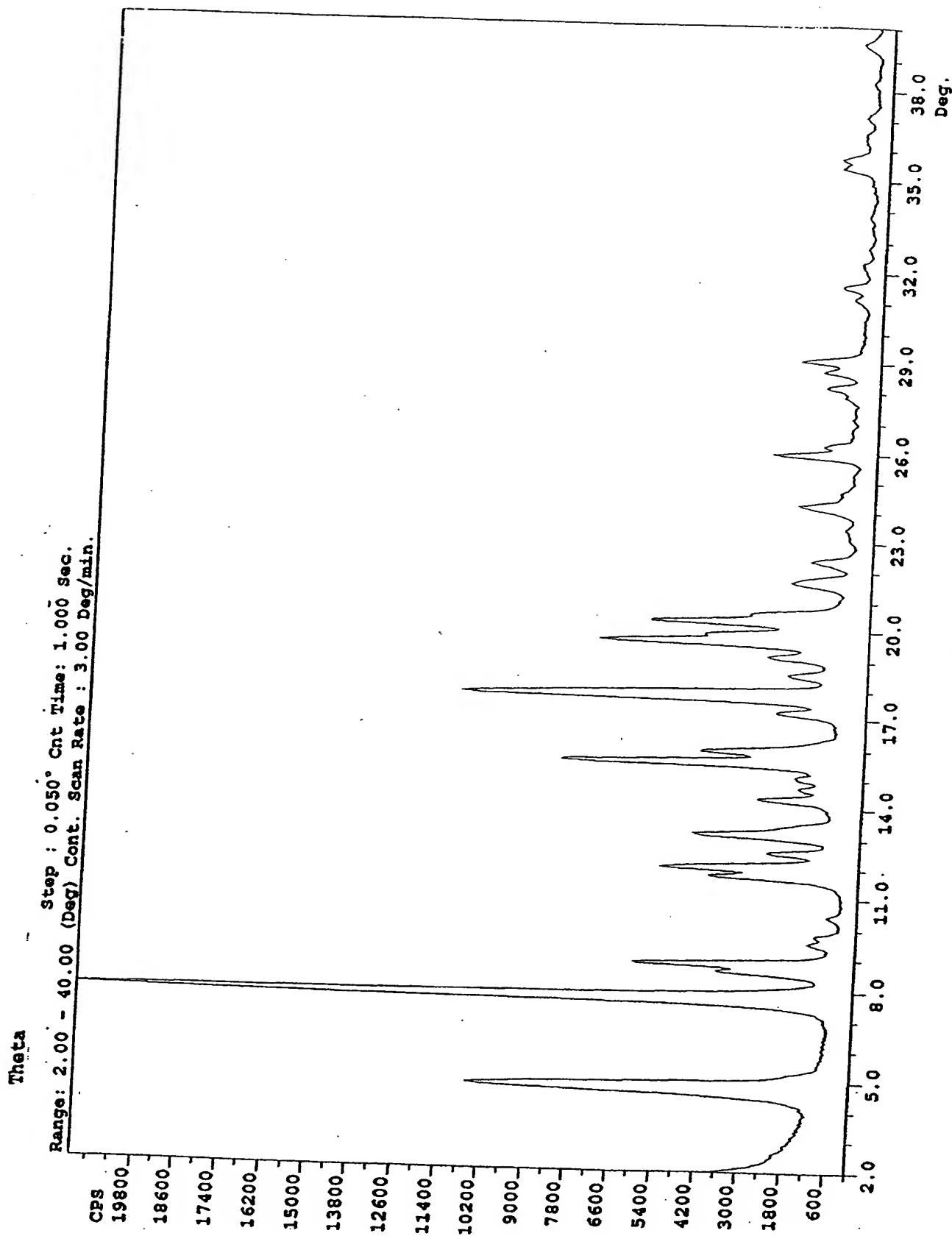
Sigma

Range: 2.00 - 40.00 (Deg) Cont. Scan Rate: 3.00 Deg/min.



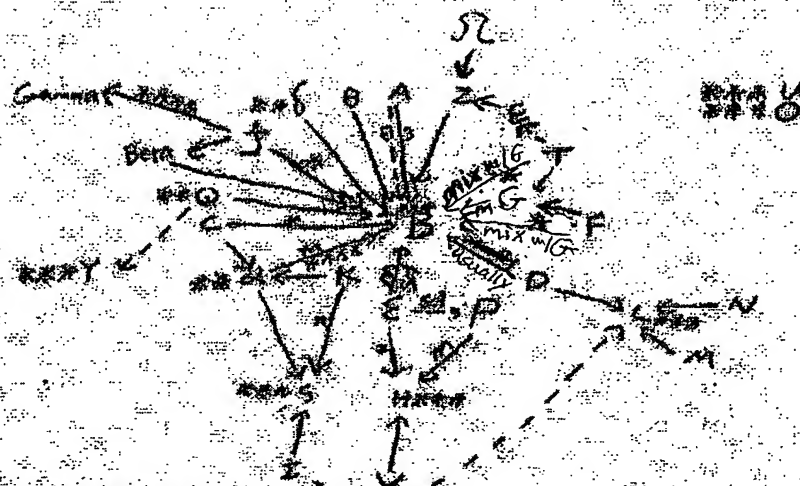
Form (5)

FIGURE 23



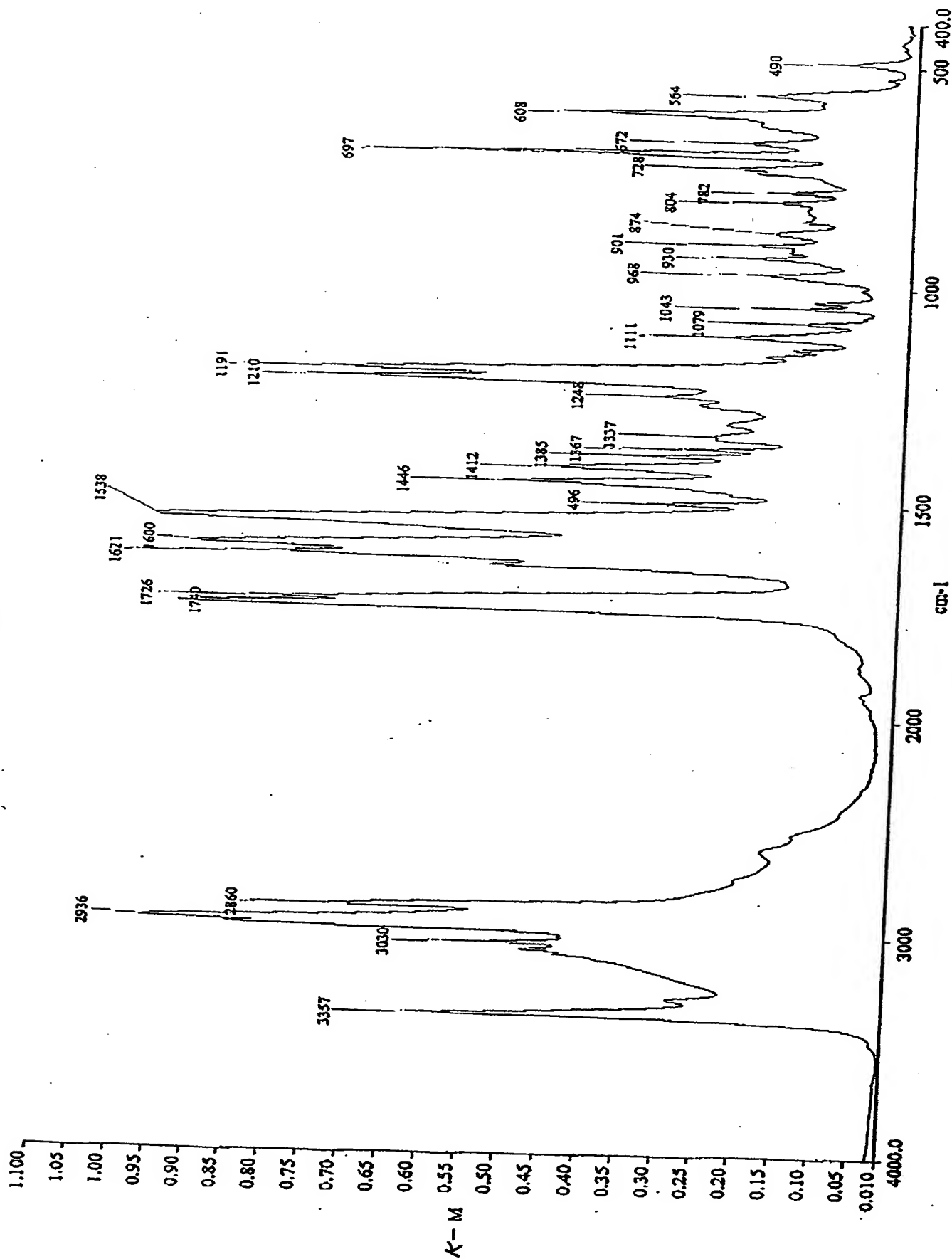
Form 2

Figure 28 - Thermal stability chart



- * Transformation may proceed through another form
- α Thermally stable at lower melting temperatures (or 50°C)
- β Thermally stable forms
- > Transformation after storage at room temperature
- m Mixture with starting form
- *** When starting material contains seeds.
- sol Results might vary depending on the solvent of form crystals used.

FIGURE 29
Form 2



-DRIFT, 4000-400 CM-1, 16 scans, Resolution: 4.00cm-1

FIGURE 30
- Form P

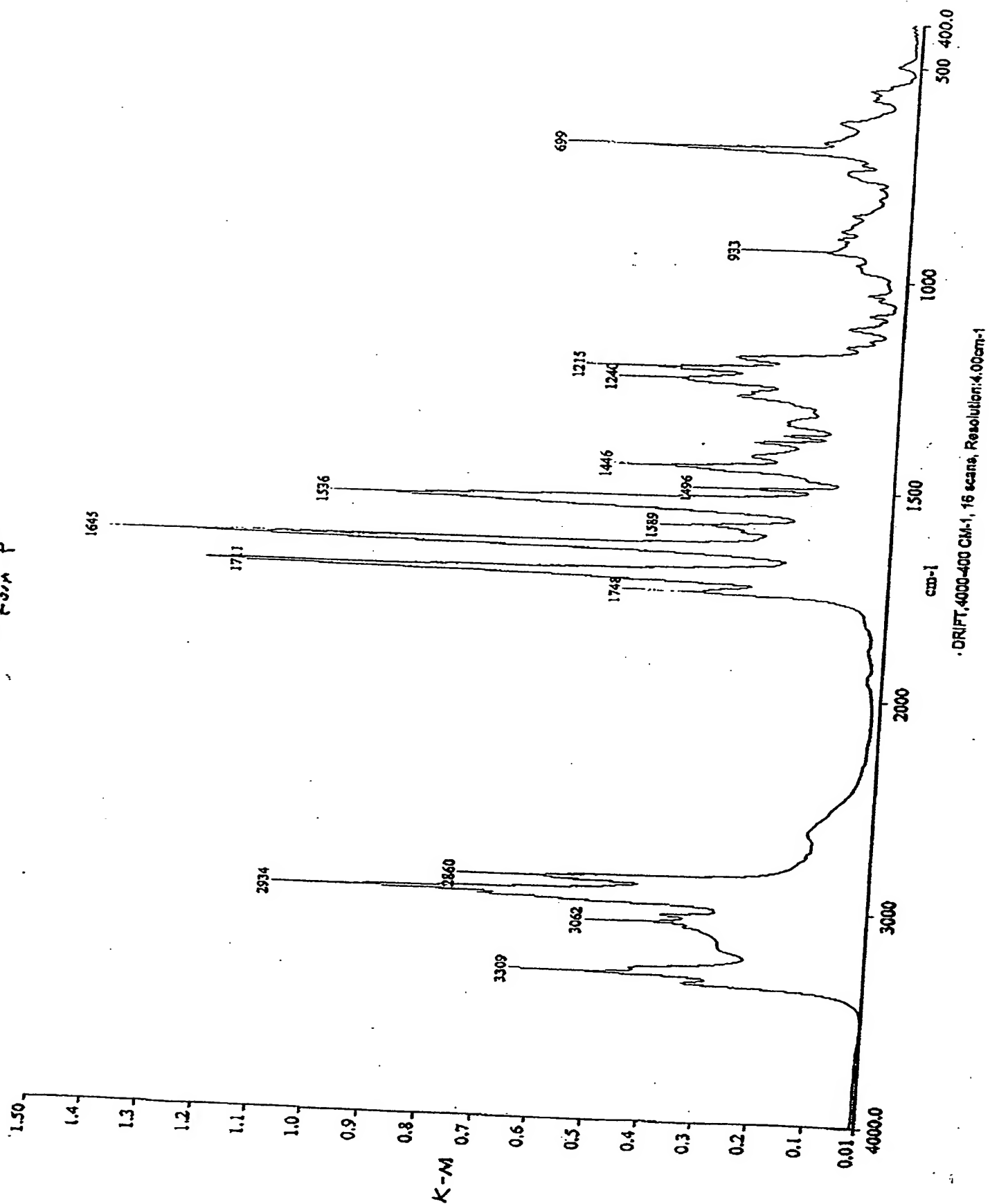
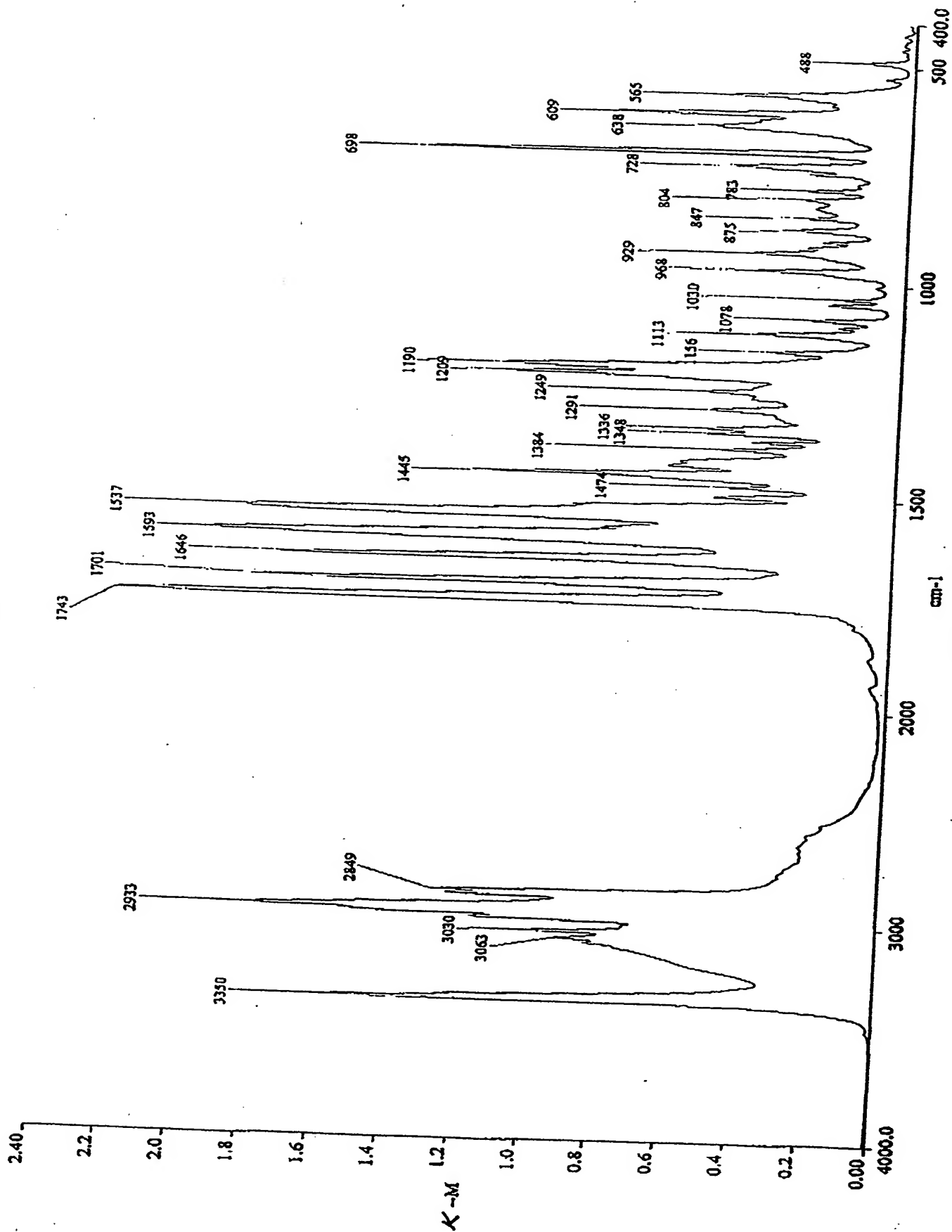


FIGURE 30
Fora U



- DRIFT, 4000-400cm⁻¹, 16 scans, resolution: 4.0cm⁻¹

Figure 32 - Nateglinide Form Z

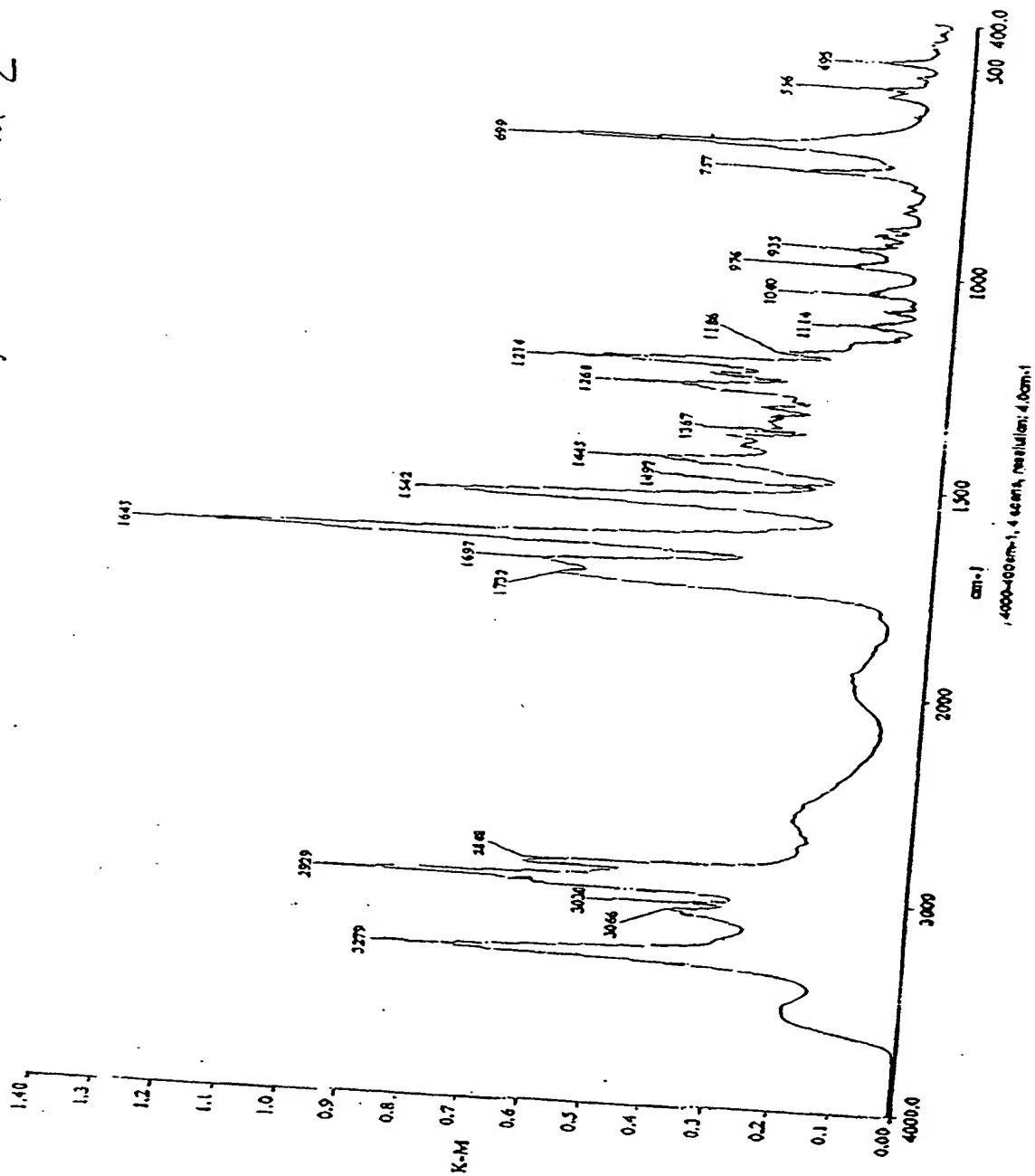
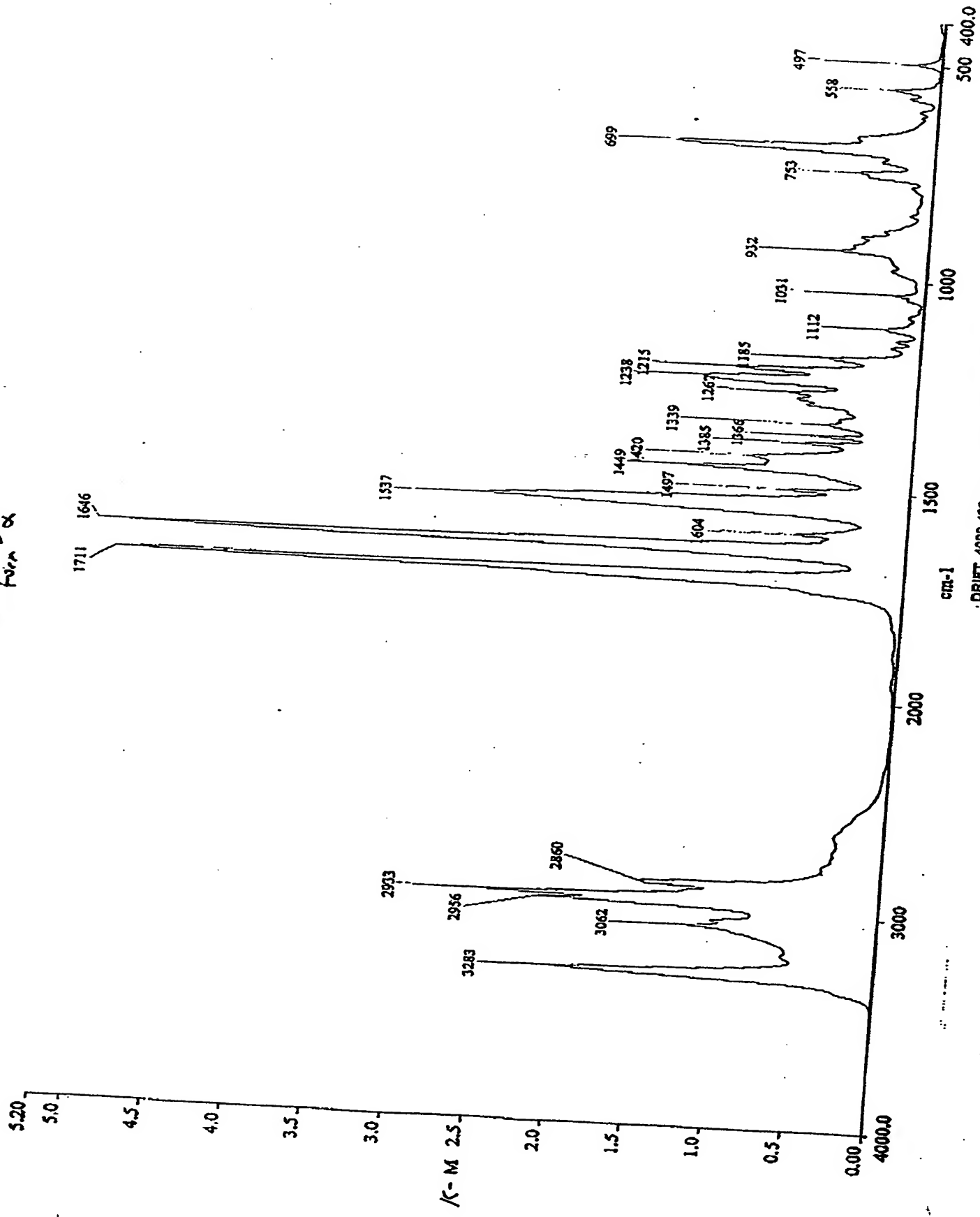
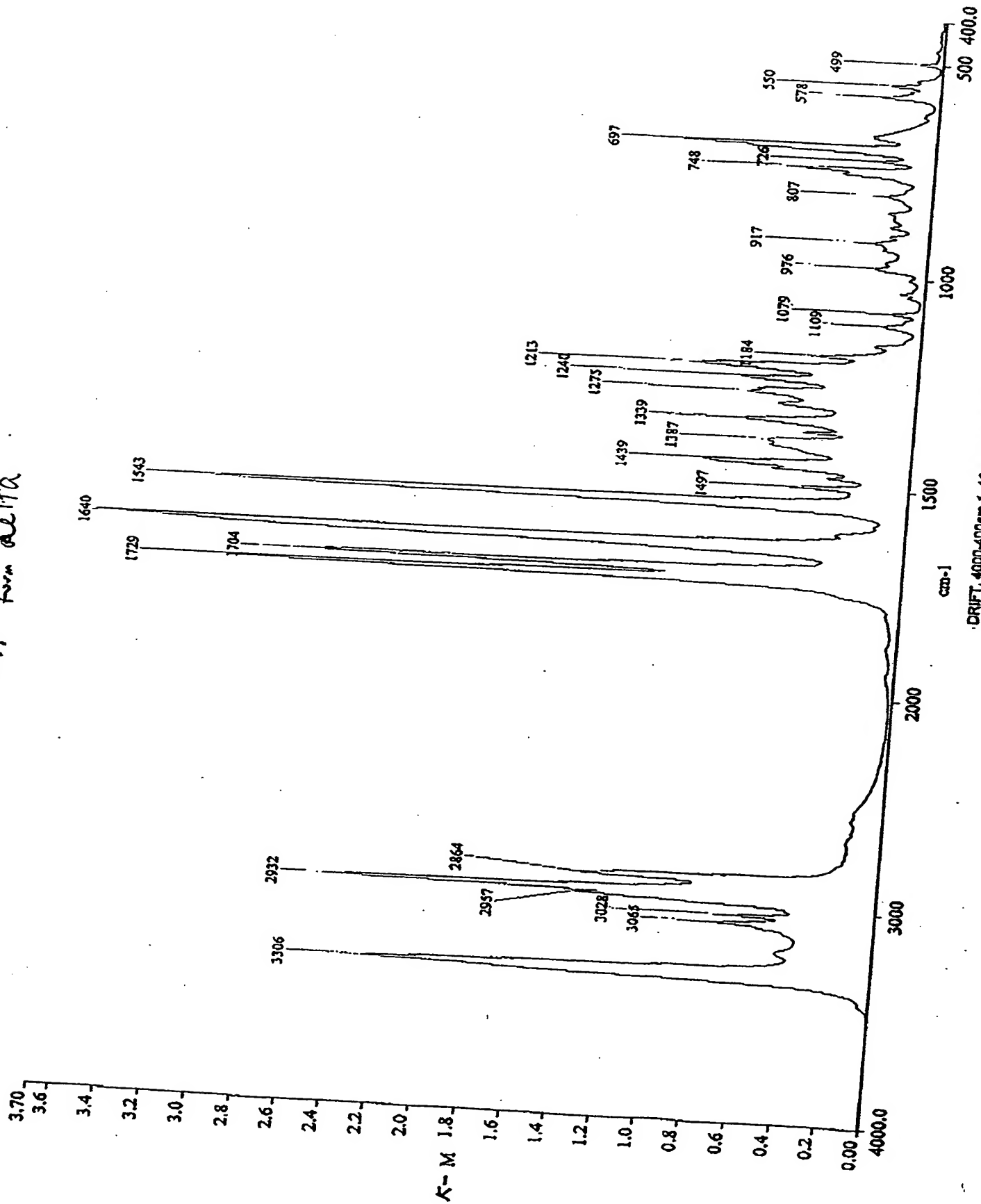


FIGURE 33
Form α



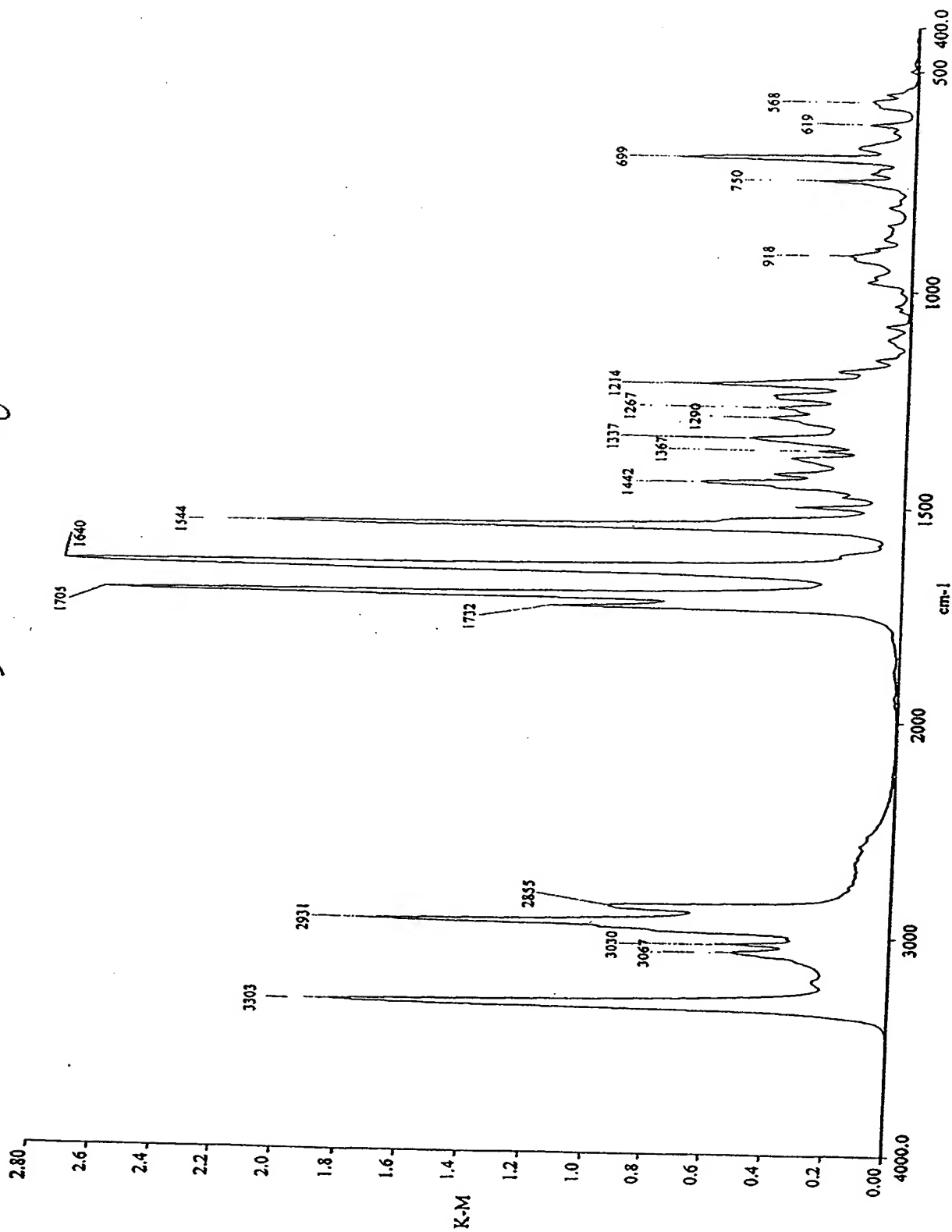
DRIFT, 4000-400 cm⁻¹, 18 scans, Resolution 4.00 cm⁻¹

FIGURE 34 Form Delta



DRIFT, 4000-400cm-1, 16 scans, resolution: 4.0cm-1

FIGURE 35 - form

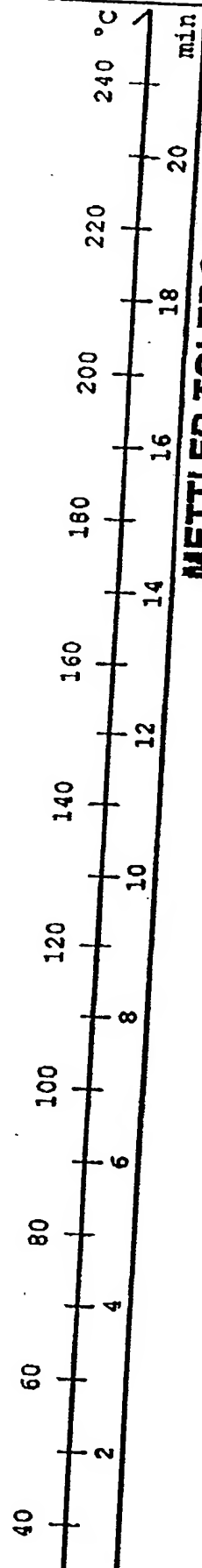


DRIFT, 4000-400CM-1, 16 SCANS RESOLUTION: 4.0CM-1

form (O)

FIGURE 36
Form A

Method: 30-250°C, 10°C/min, 40 ml/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 ml/min



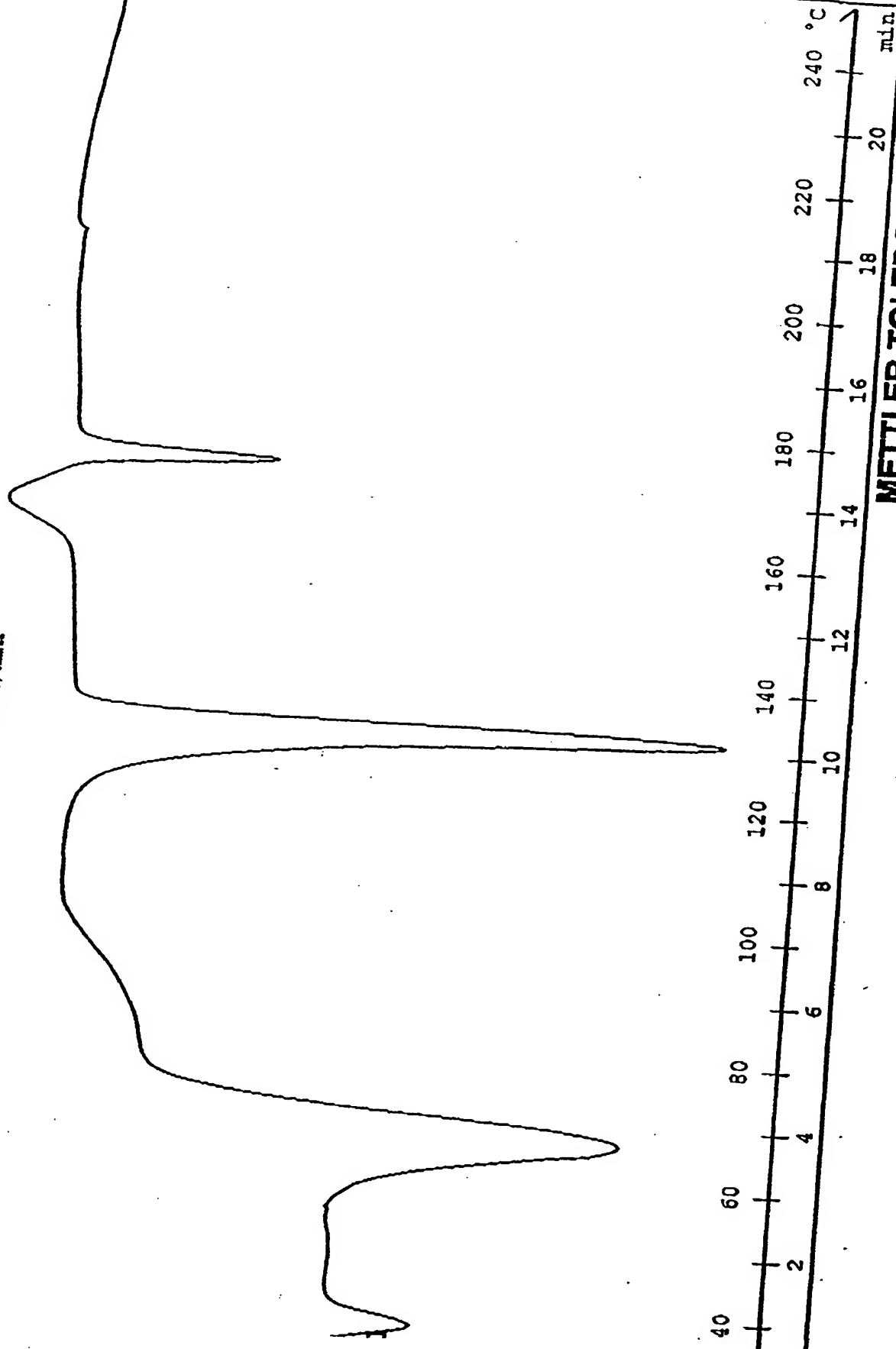
METTLER TOLEDO STAR® System

FIGURE 37

Form D

Method: 30-250°C, 10°C/min, 40ml/min N₂
30.0-250.0°C 10.00°C/min

N₂, 40.0 ml/min



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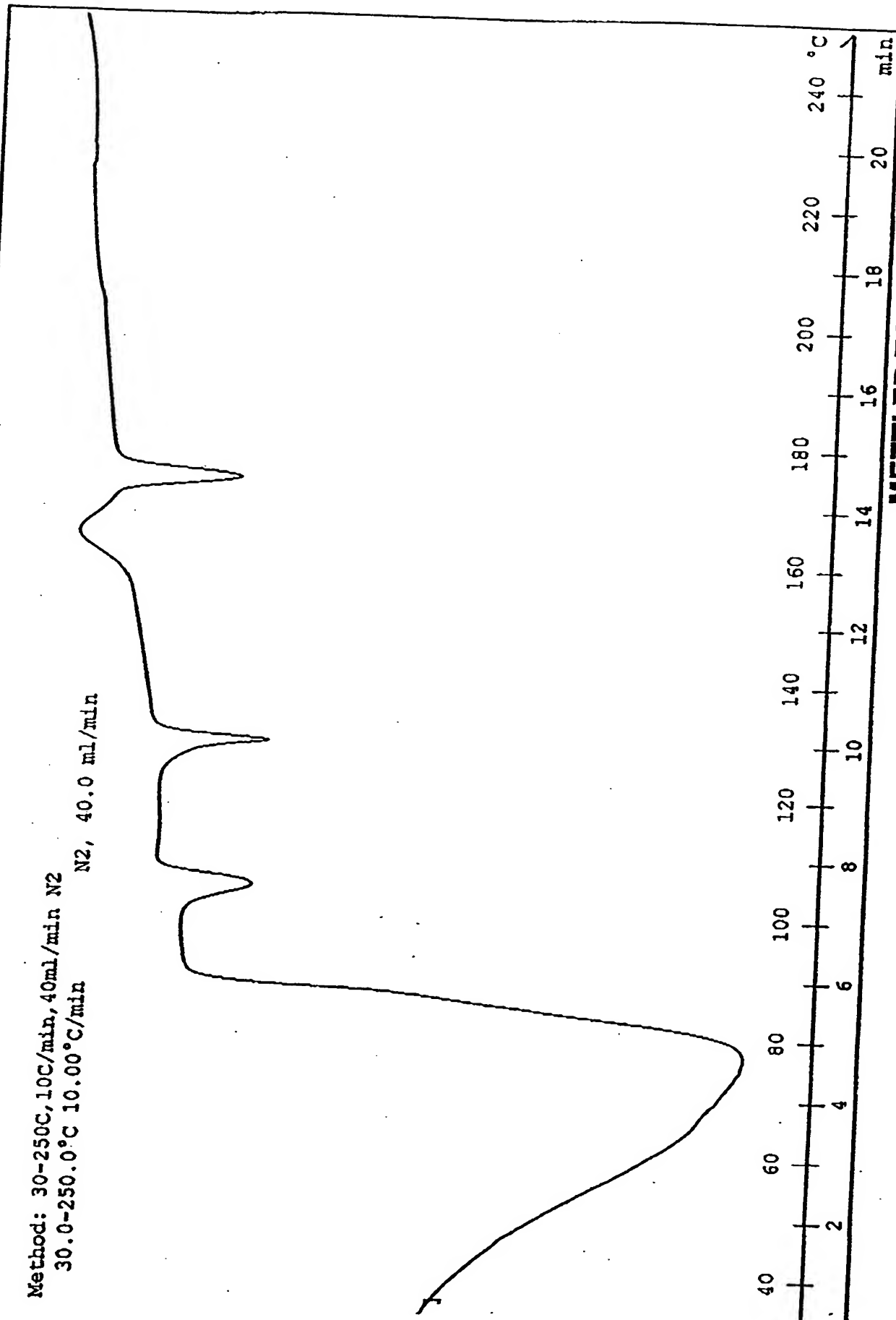
FIGURE 38

Form E

Method: 30-250C, 10C/min, 40ml/min N2

30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min

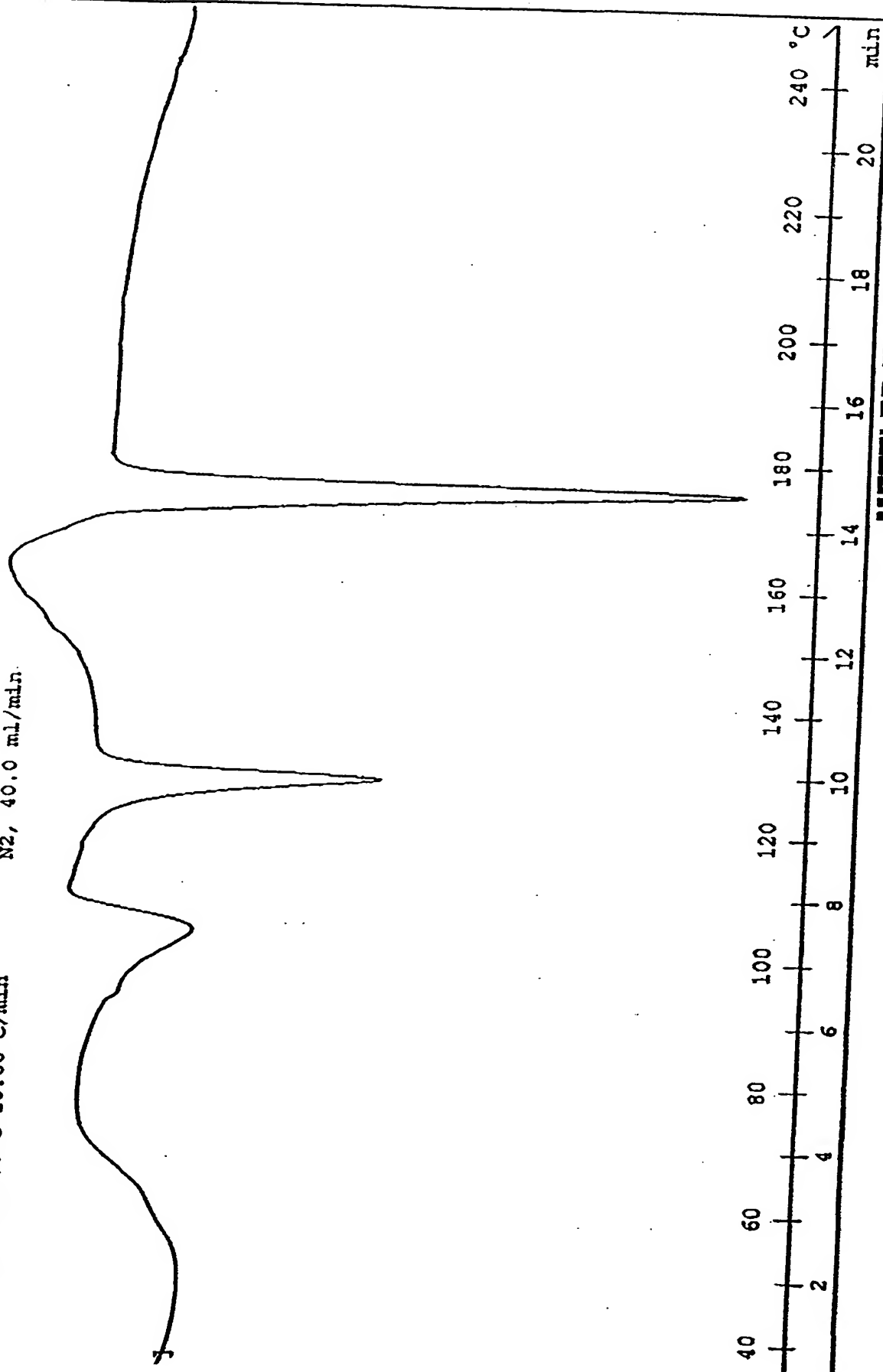


METTLER TOLEDO STAR® System

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FIGURE 1

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min



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FIGURE 88

IXO

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min

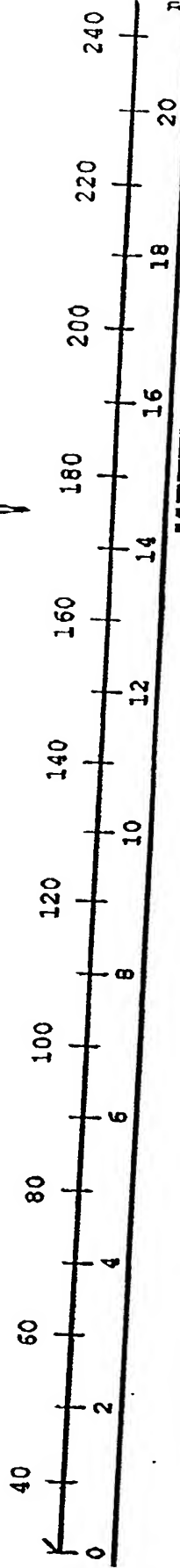
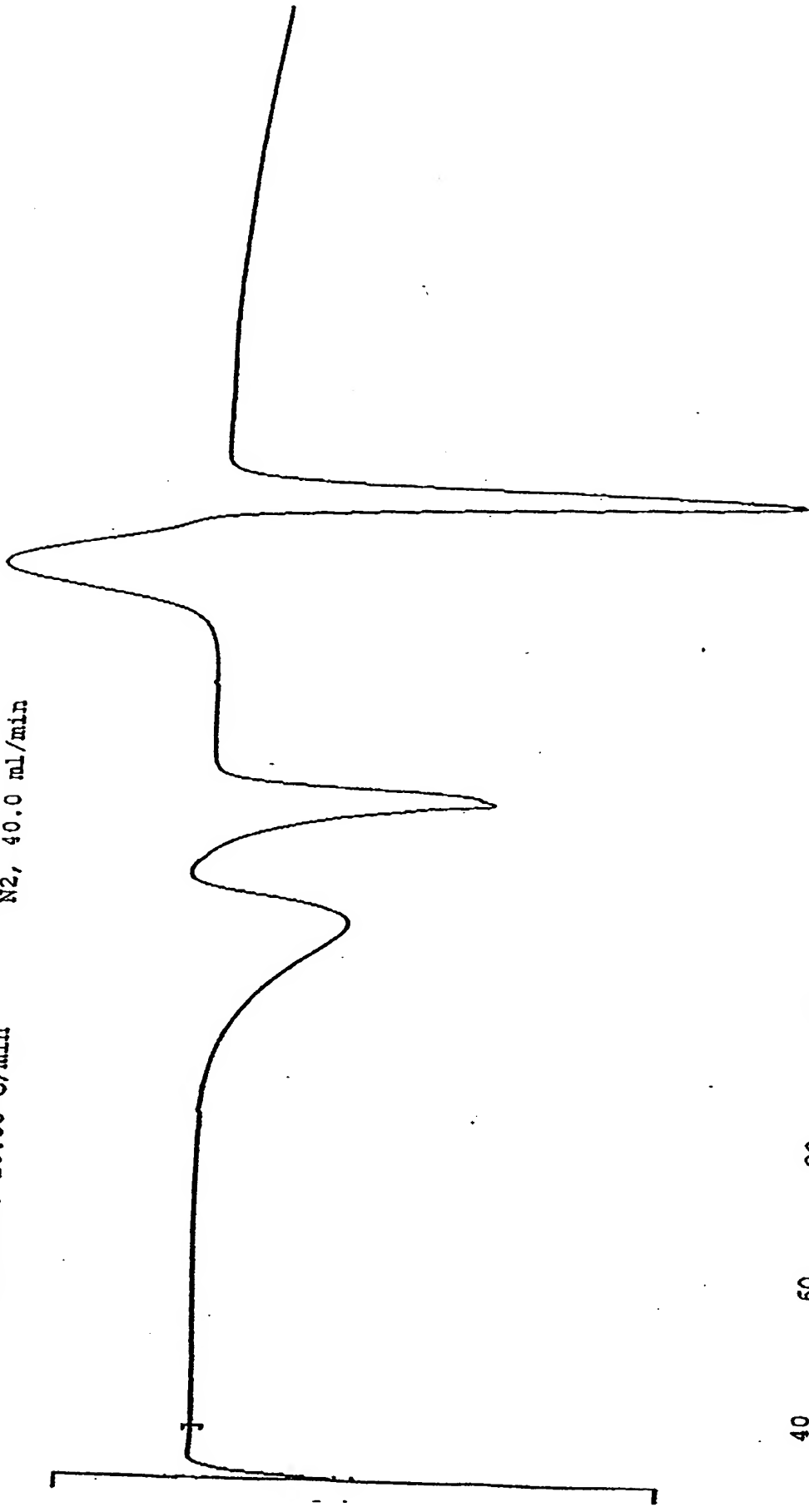
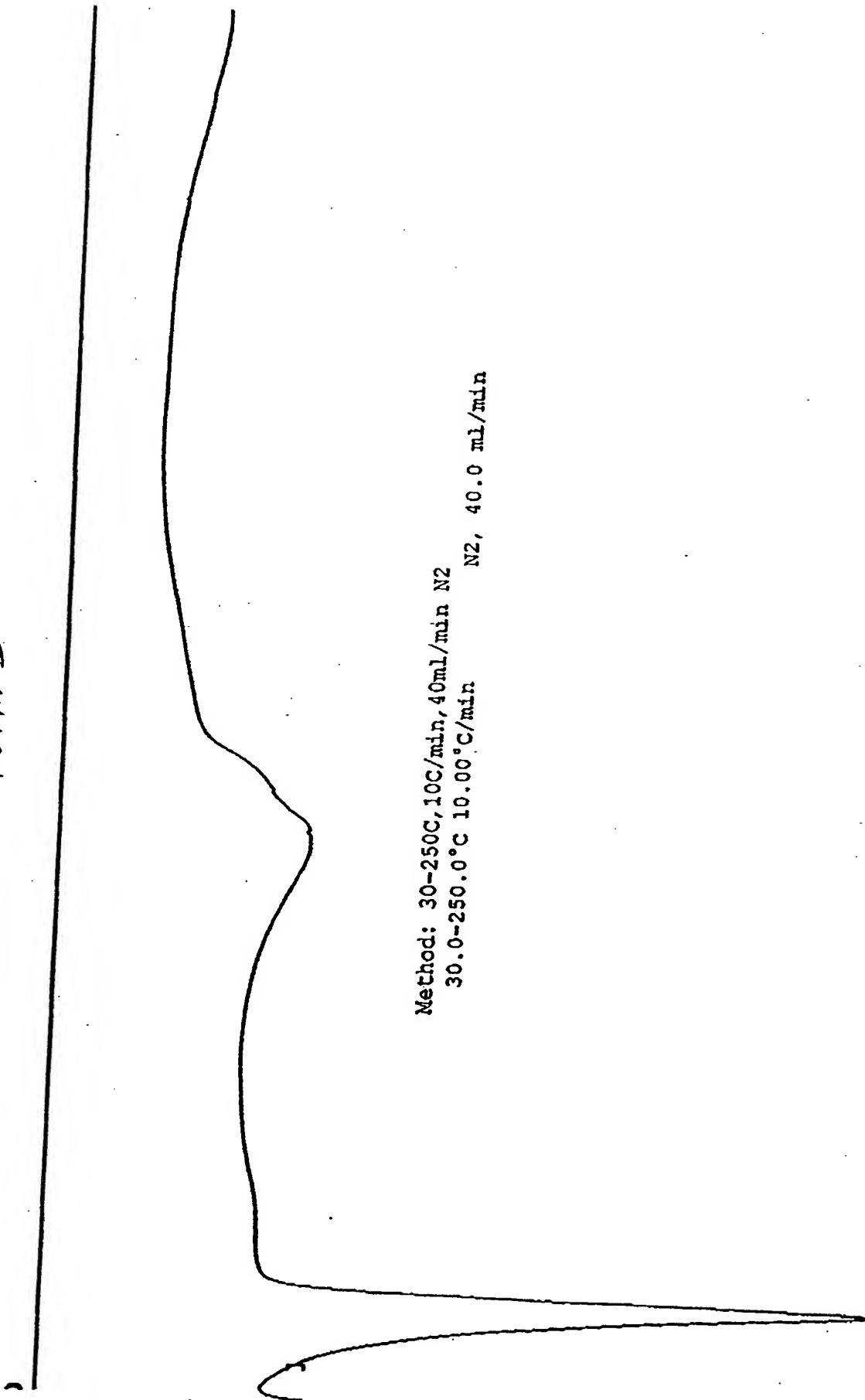
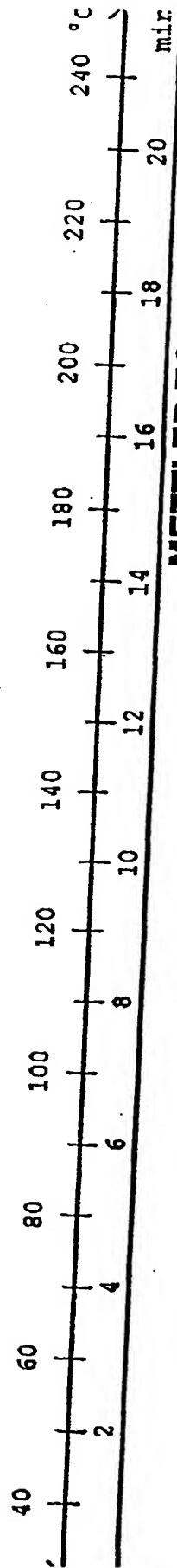


FIGURE 2041

Form I



Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min
N2, 40.0 ml/min



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FIGURE 4d

Form J

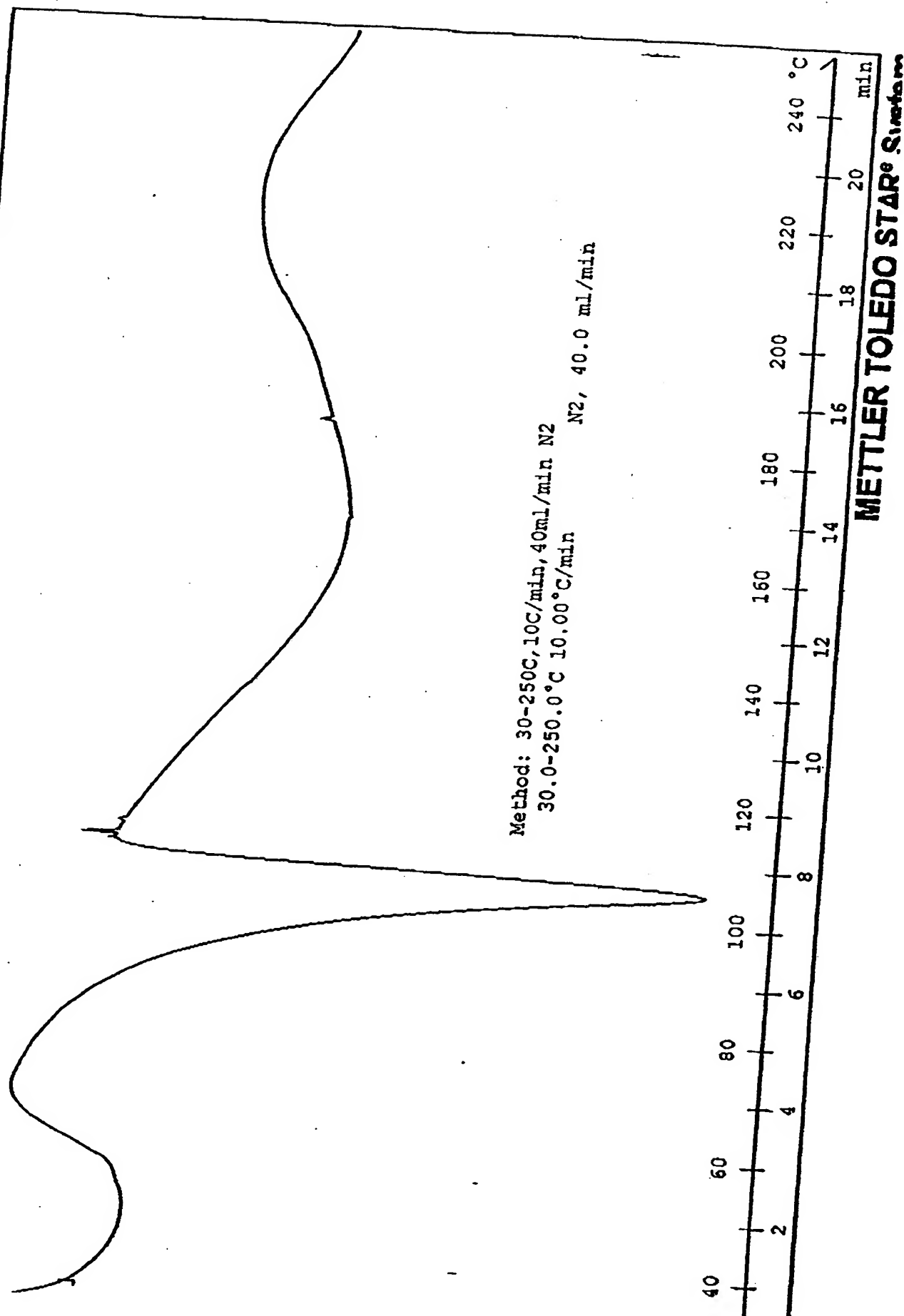


FIGURE 43
Form K

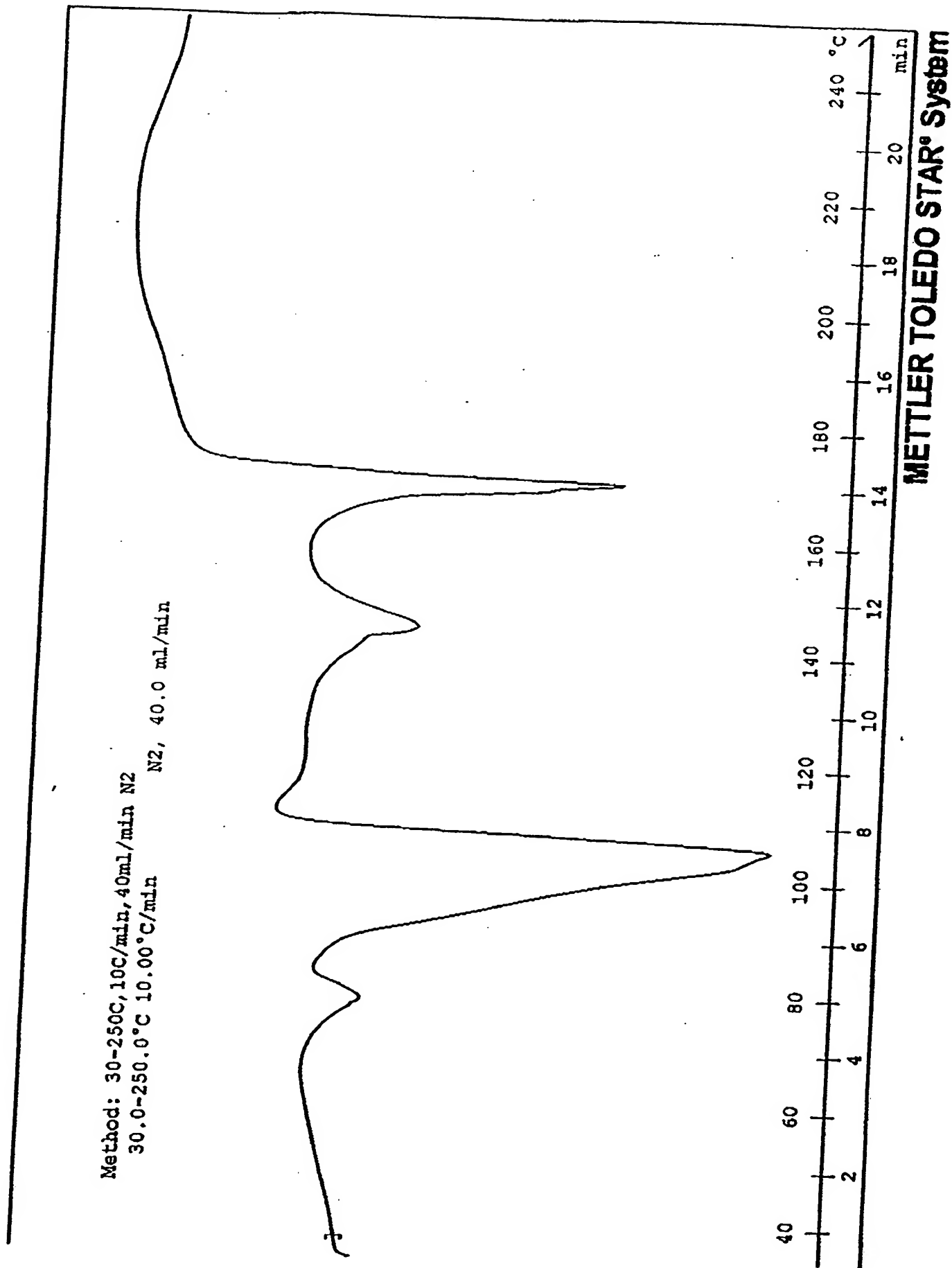
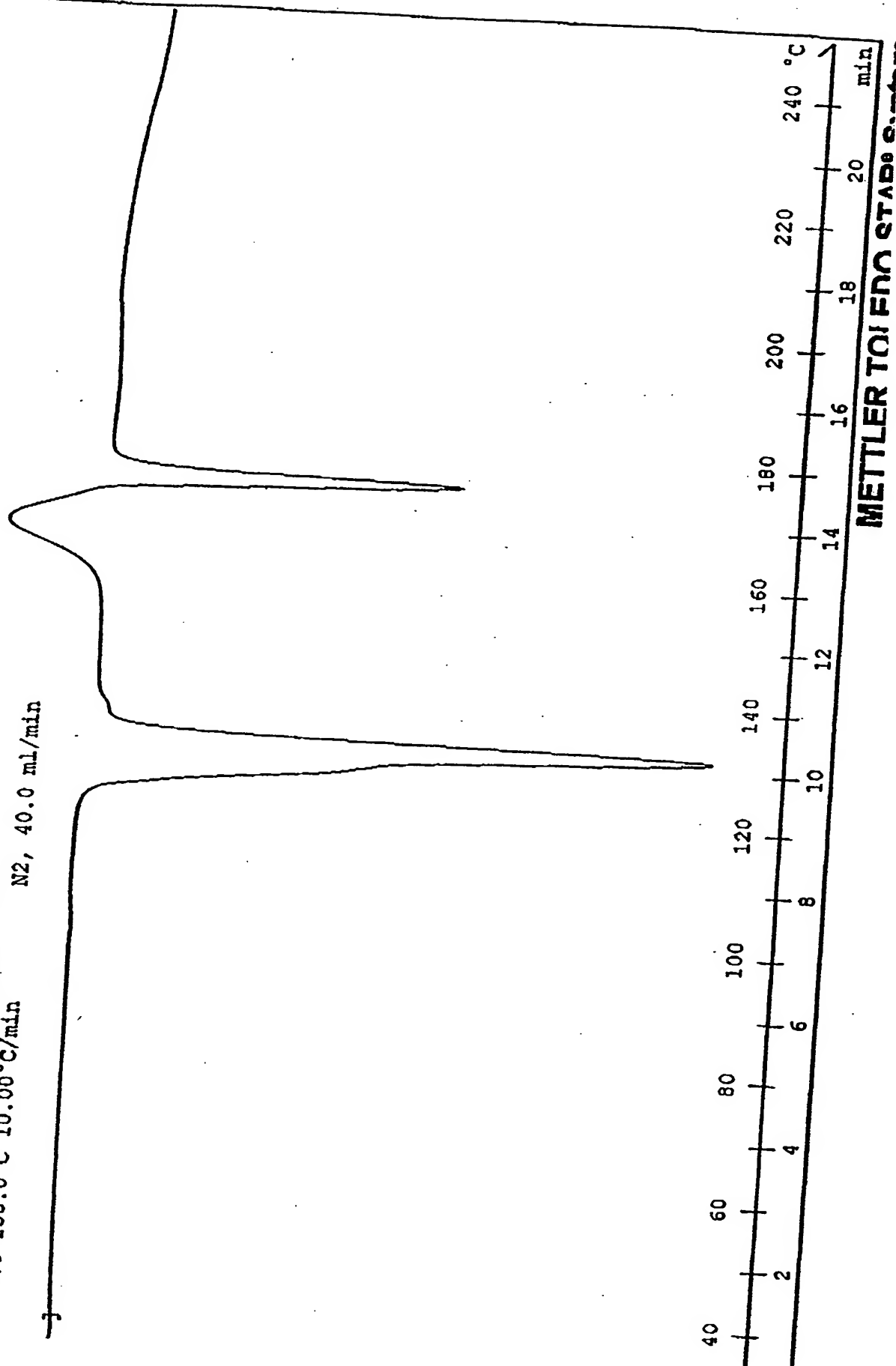


FIGURE 42
4/4
Form L

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min

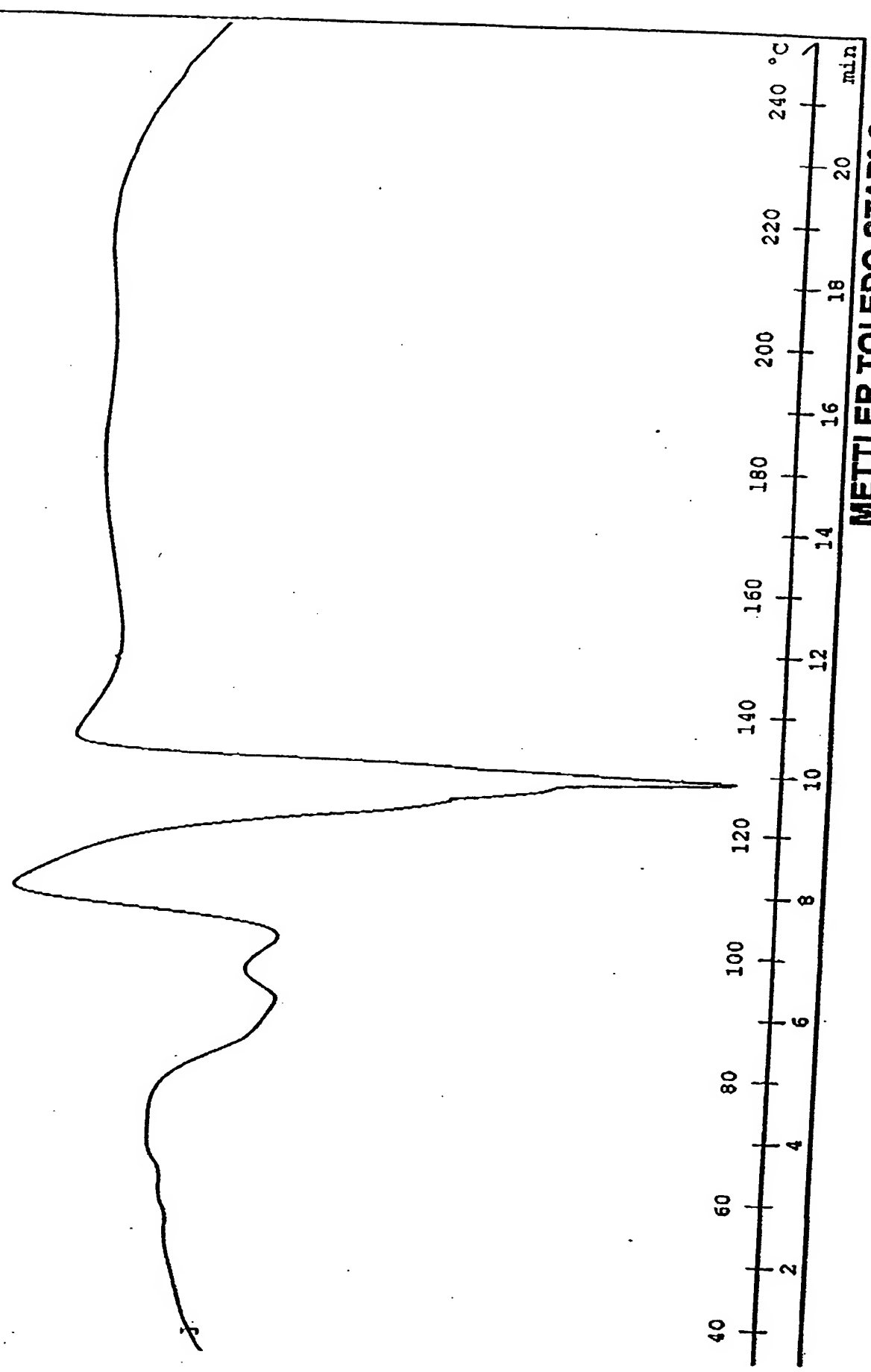
N2, 40.0 ml/min



METTLER TOLEDO STABLO 6.11

FIGURE 45
Form M

Method: 30-250°C, 10°C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min



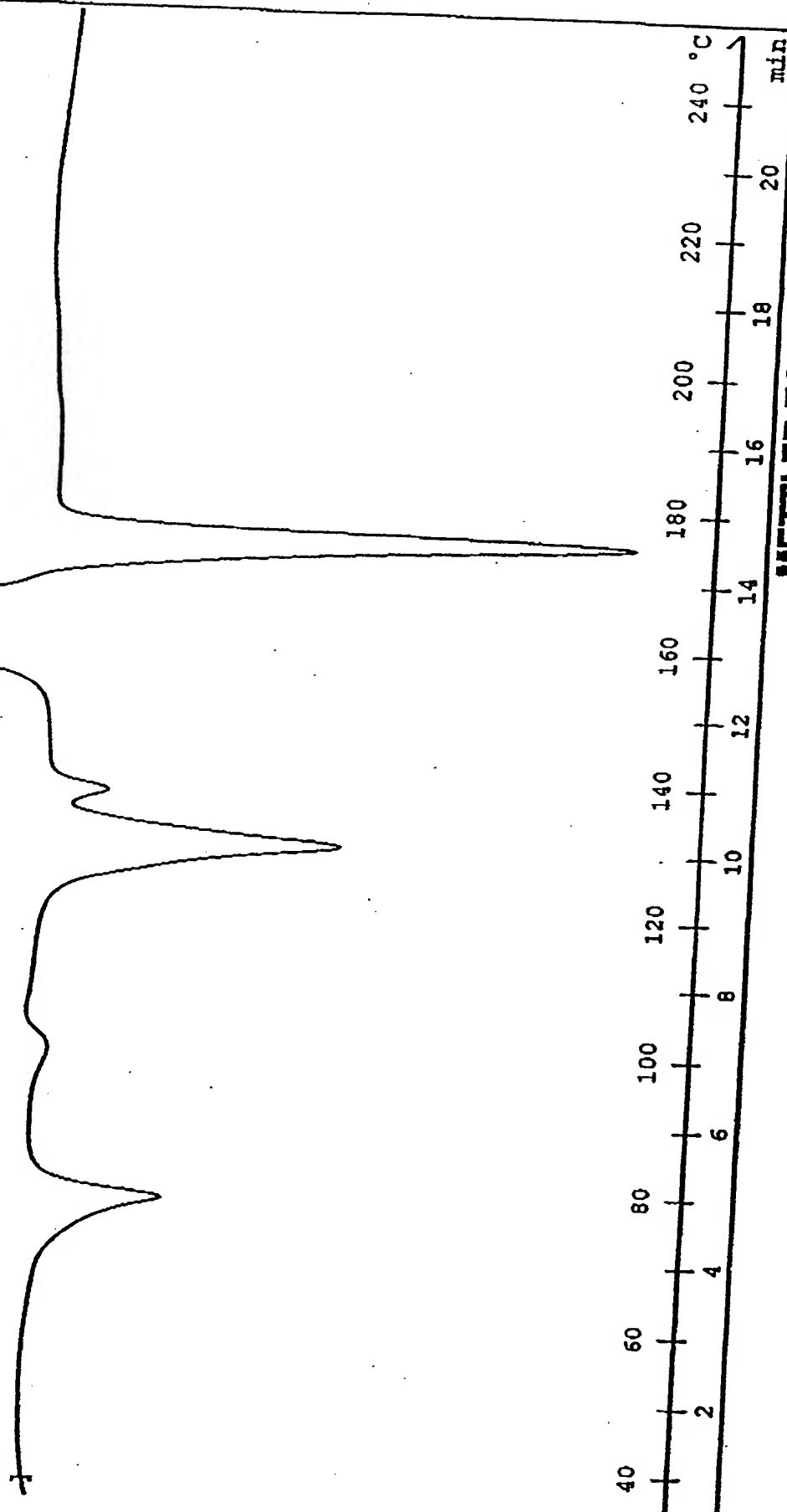
METTTLER TOLEDO STAR® System

FIGURE 44 4/6

Form N

Method: 30-250°C, 10°C/min, 40 ml/min N₂
30.0-250.0°C 10.00°C/min

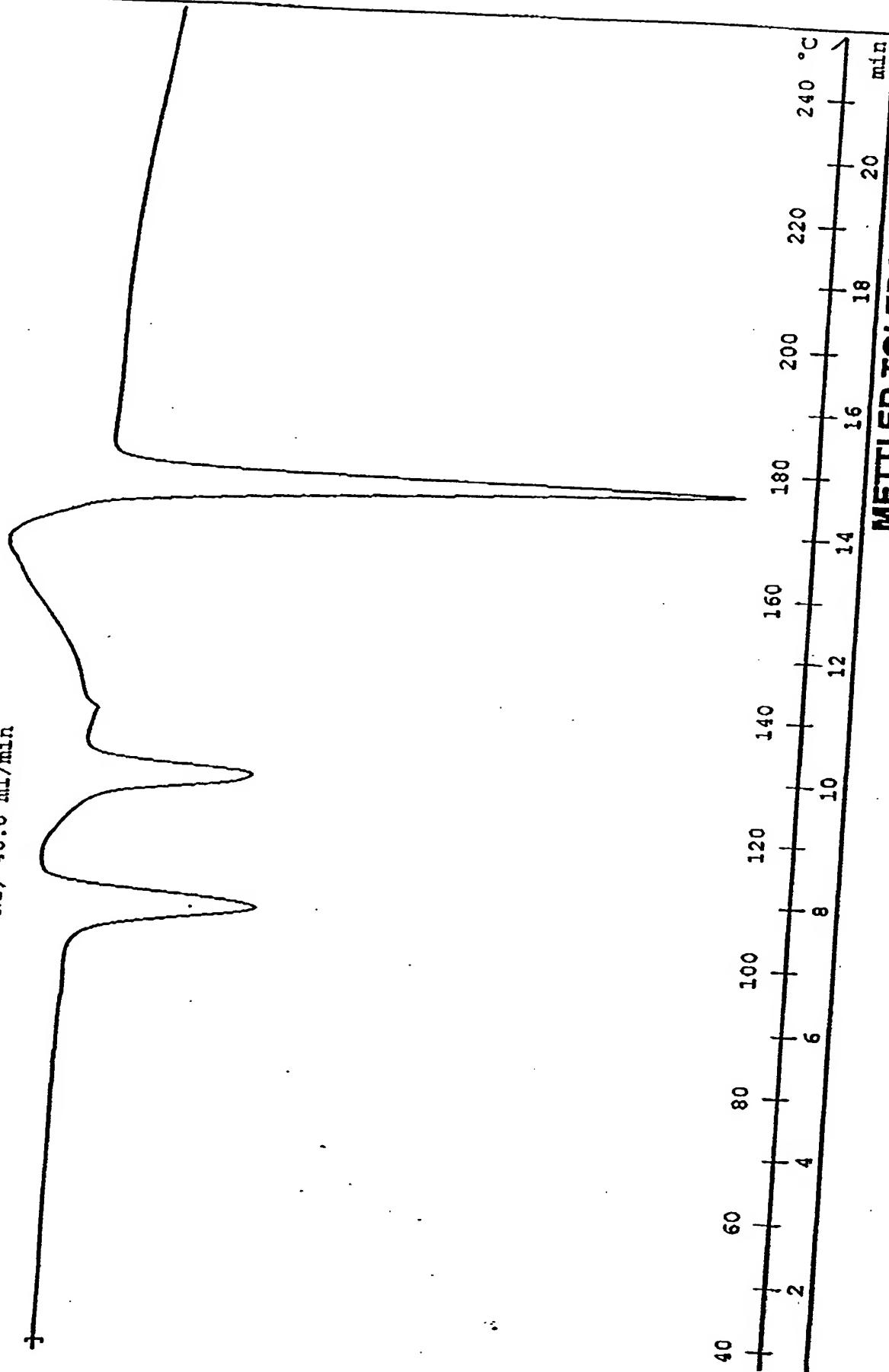
N₂, 40.0 ml/min



METTLER TOLEDO STAR® System

Figure 48
Form P

Method: 30-250°C, 10°C/min, 40 mL/min N₂
30.0-250.0°C 10.00°C/min
N₂, 40.0 mL/min



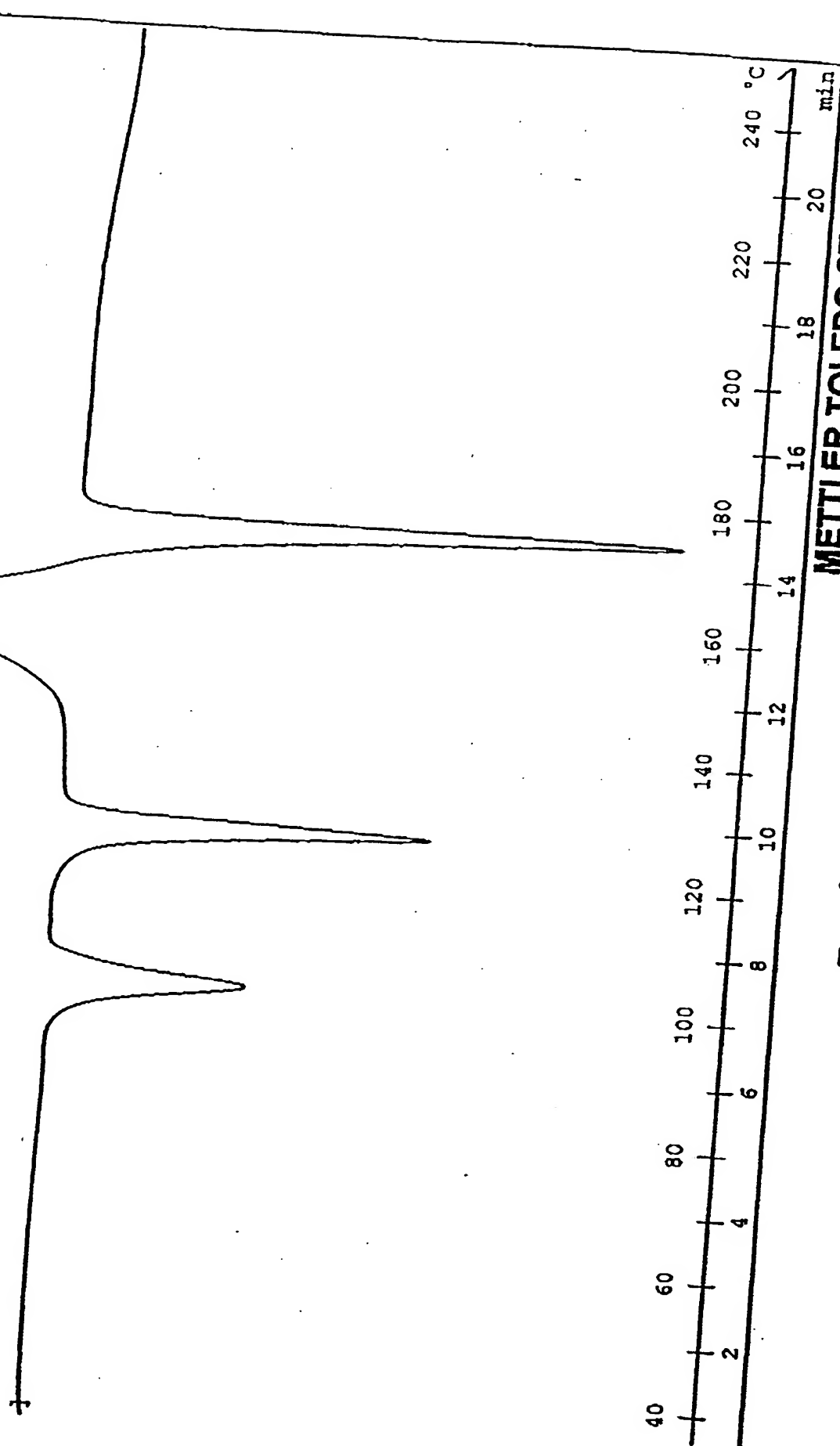
METTLER TOLEDO STAR® System

FIGURE 47 49

Form Q

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min

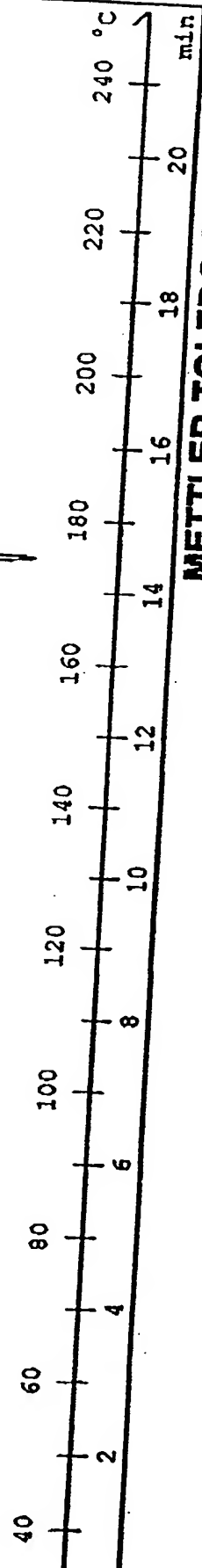


METTTLER TOLEDO STAR® System

FIGURE 48-50
Form T

Method: 30-250°C, 10°C/min, 40 mL/min N₂
30.0-250.0°C 10.00°C/min

N₂, 40.0 mL/min



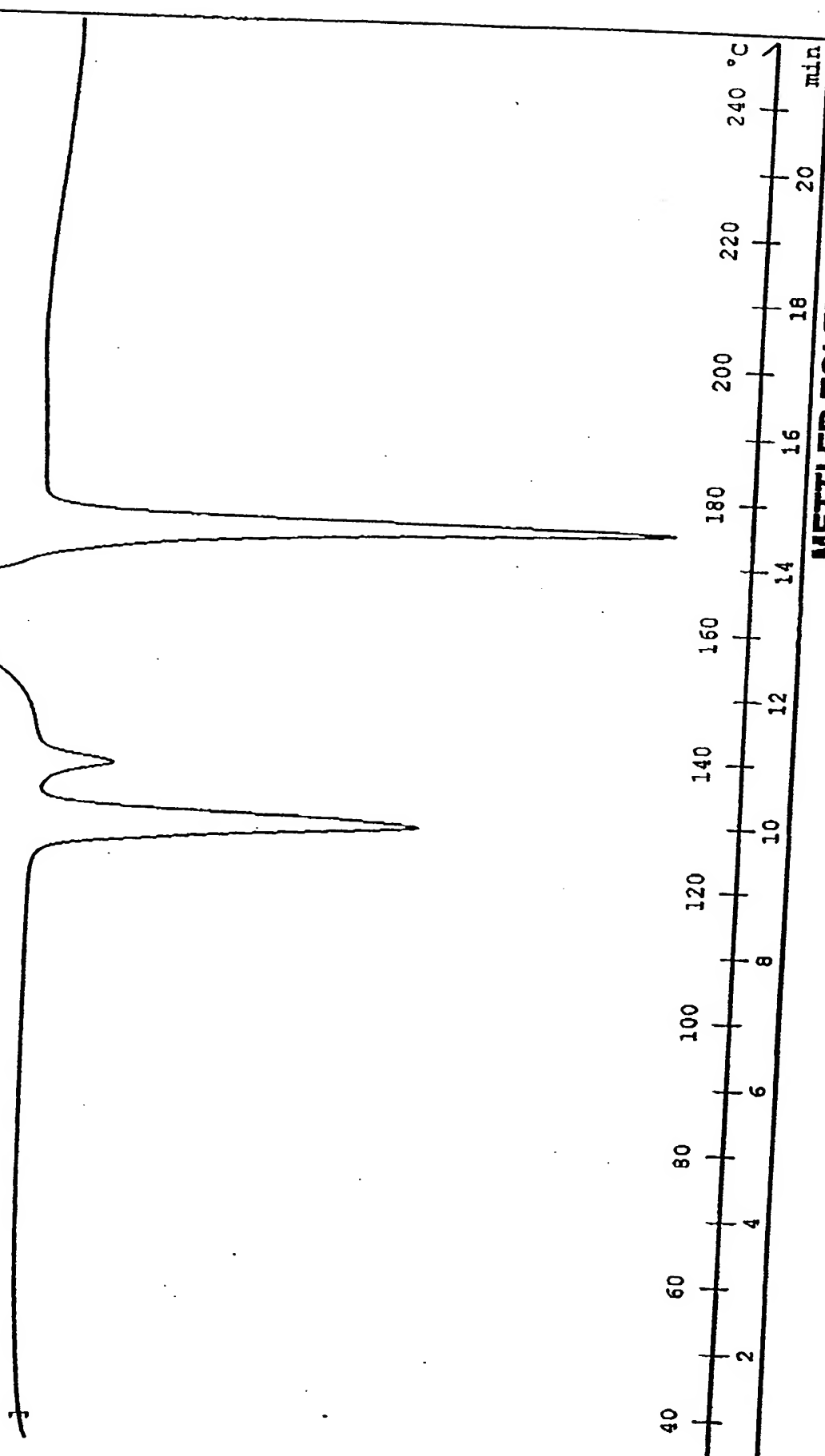
METTLER TOLEDO STAR® System

FIGURE 49. 51

Form 1A

Method: 30-250°C, 10°C/min, 40 ml/min N₂
30.0-250.0°C 10.00°C/min

N₂, 40.0 ml/min

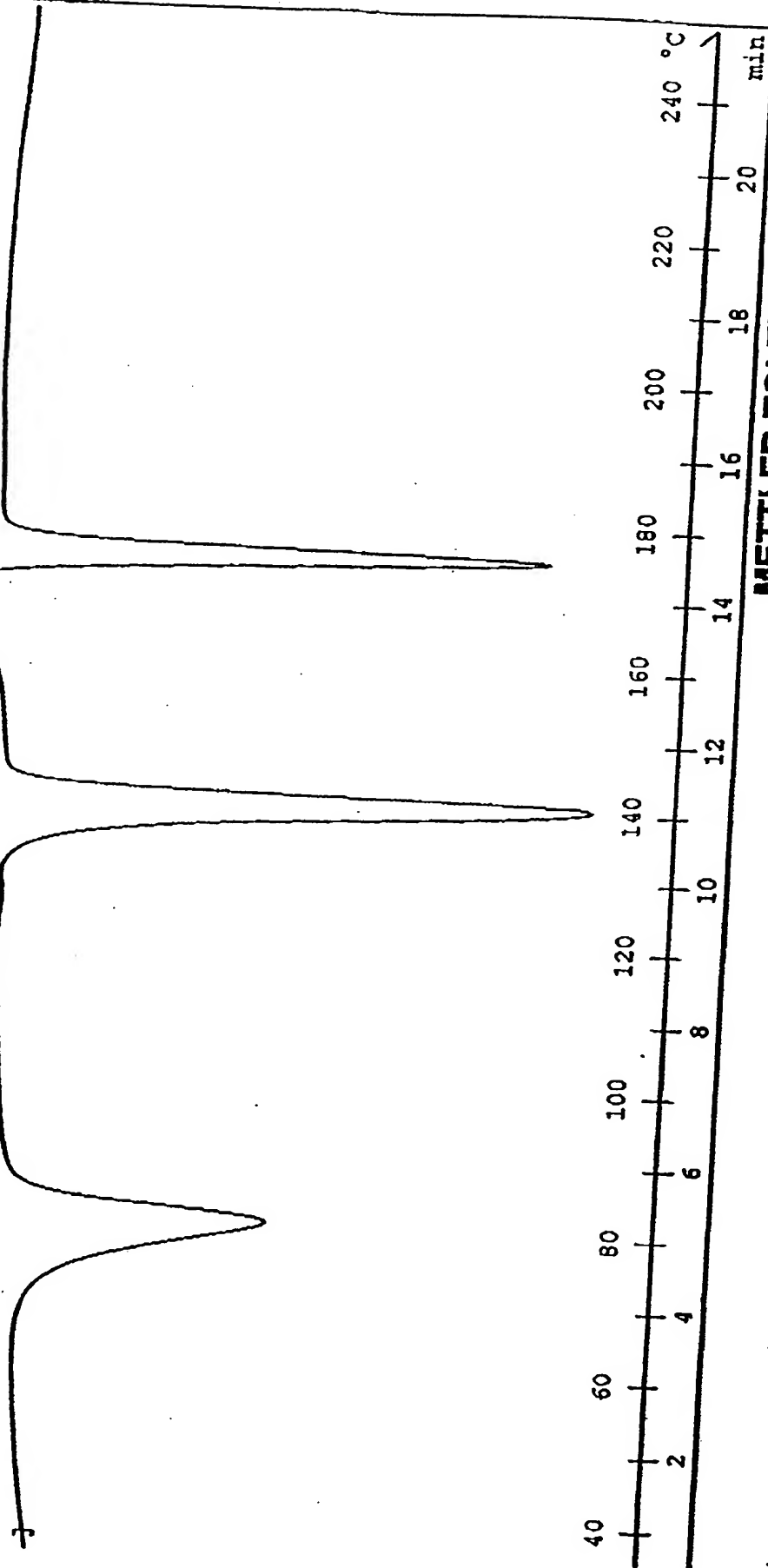


METTTLER TOLEDO STAR® System

FIGURE 5052
Form V

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min

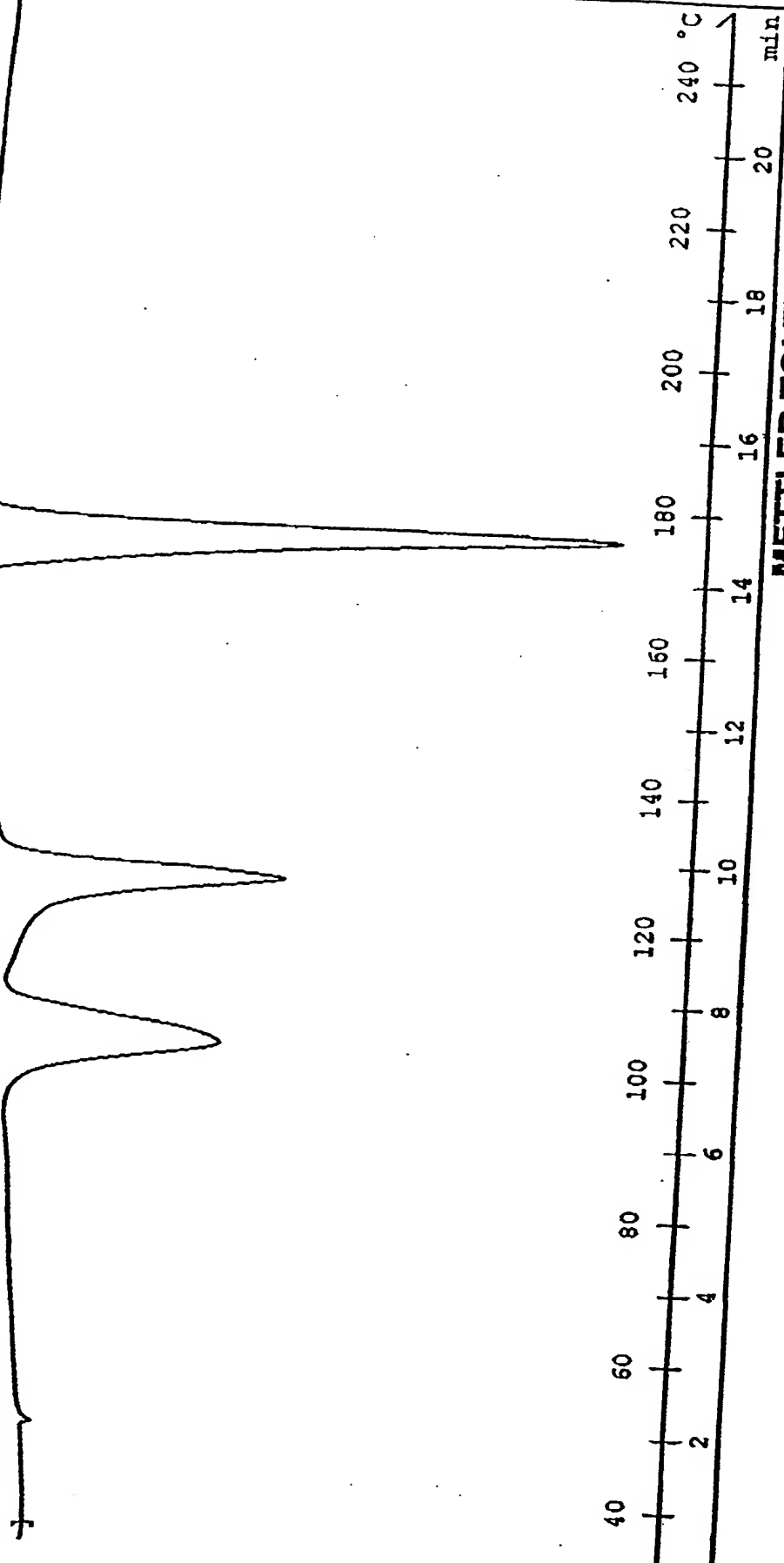
N2, 40.0 ml/min



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FIGURE 52-53
Form Y (chloroform solvent)

Method: 30-250°C, 10°C/min, 40 ml/min N2
30.0-250.0°C 10.00°C/min
N2, 40.0 ml/min

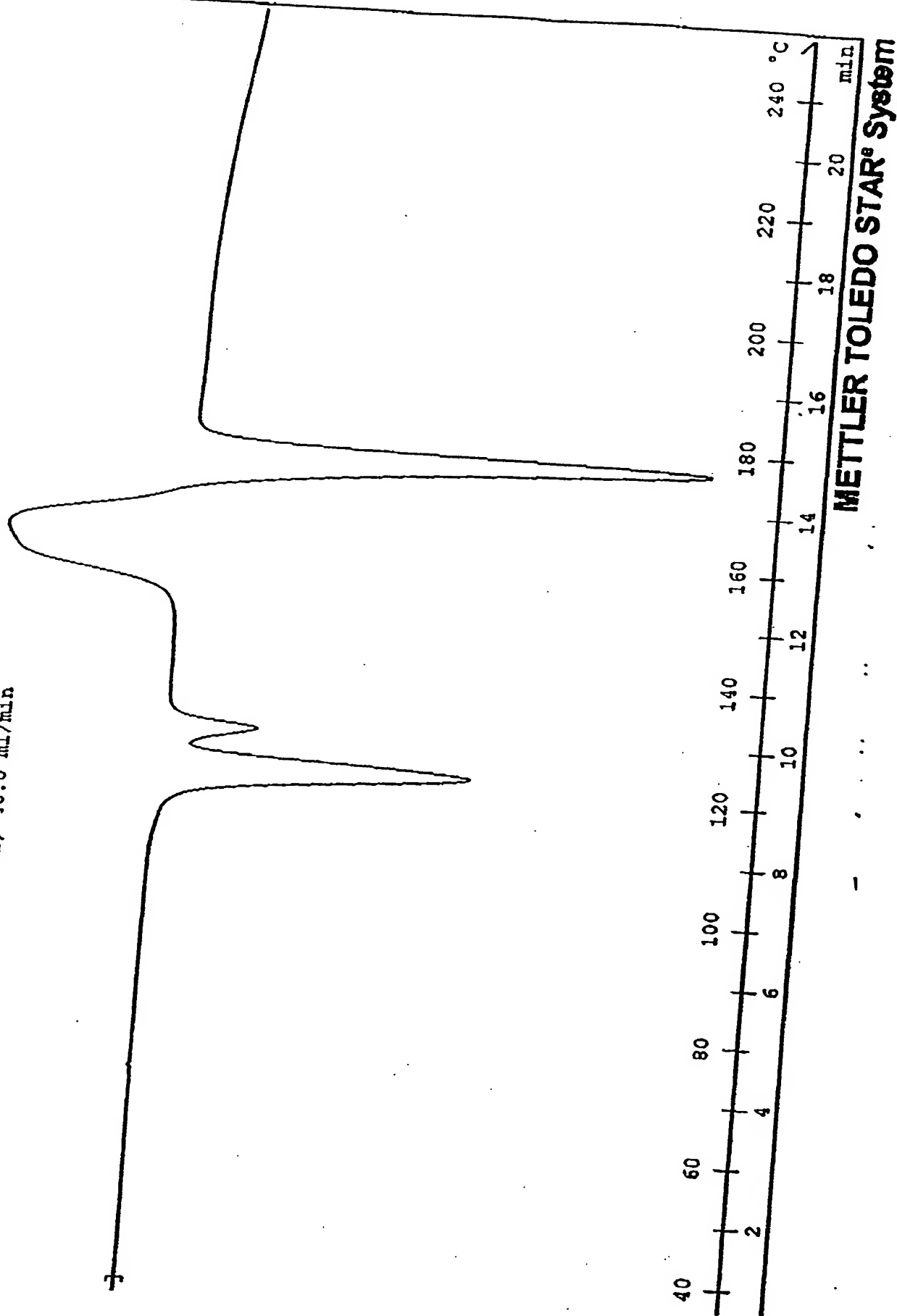


METTLER TOLEDO STAR® System

FIGURE 5.4
Y (dichloromethane solvate)

Method: 30-250°C, 10°C/min, 40 mL/min N₂
30.0-250.0°C 10.00°C/min

N₂, 40.0 mL/min



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Figure 27 - Nateglinide Form 2

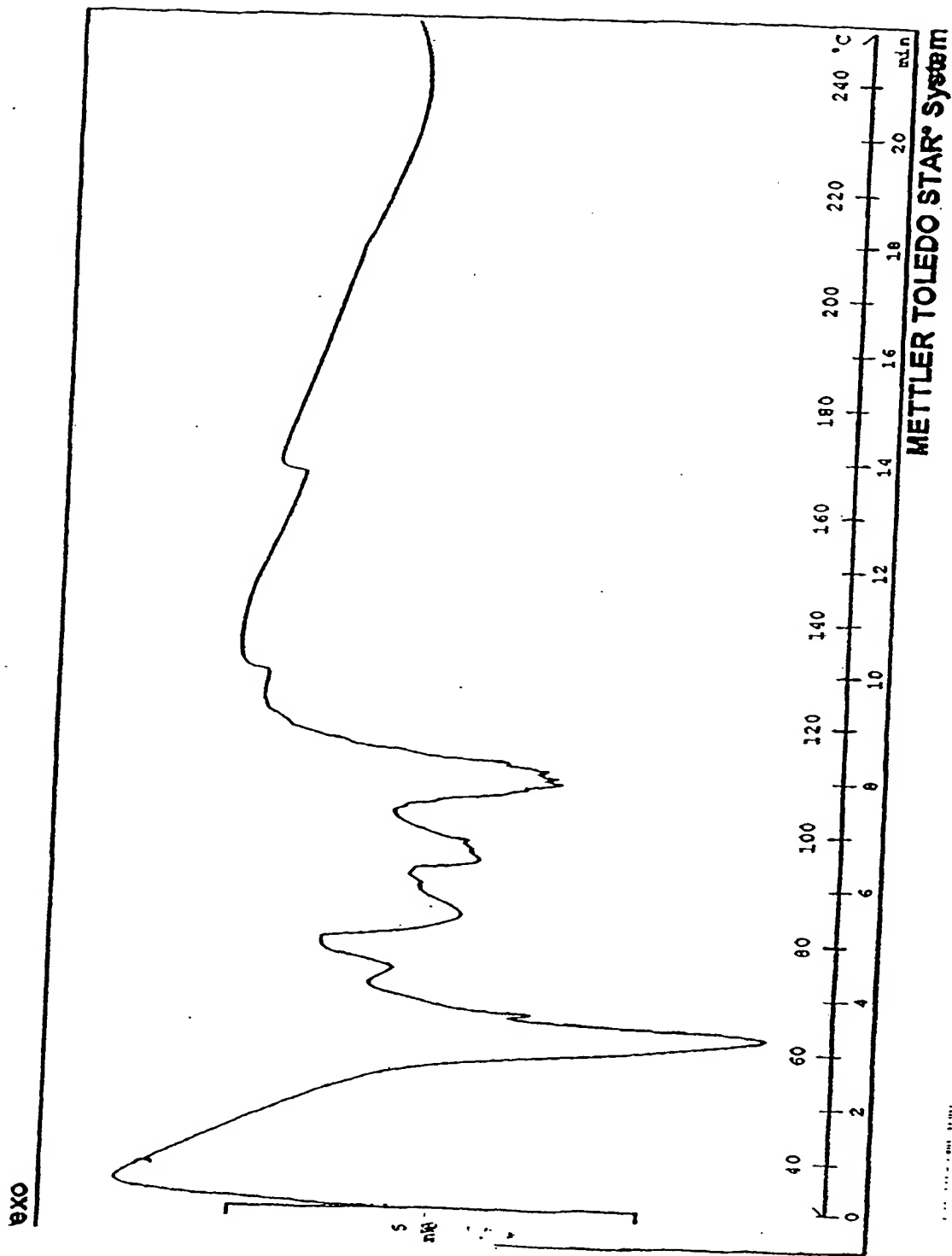
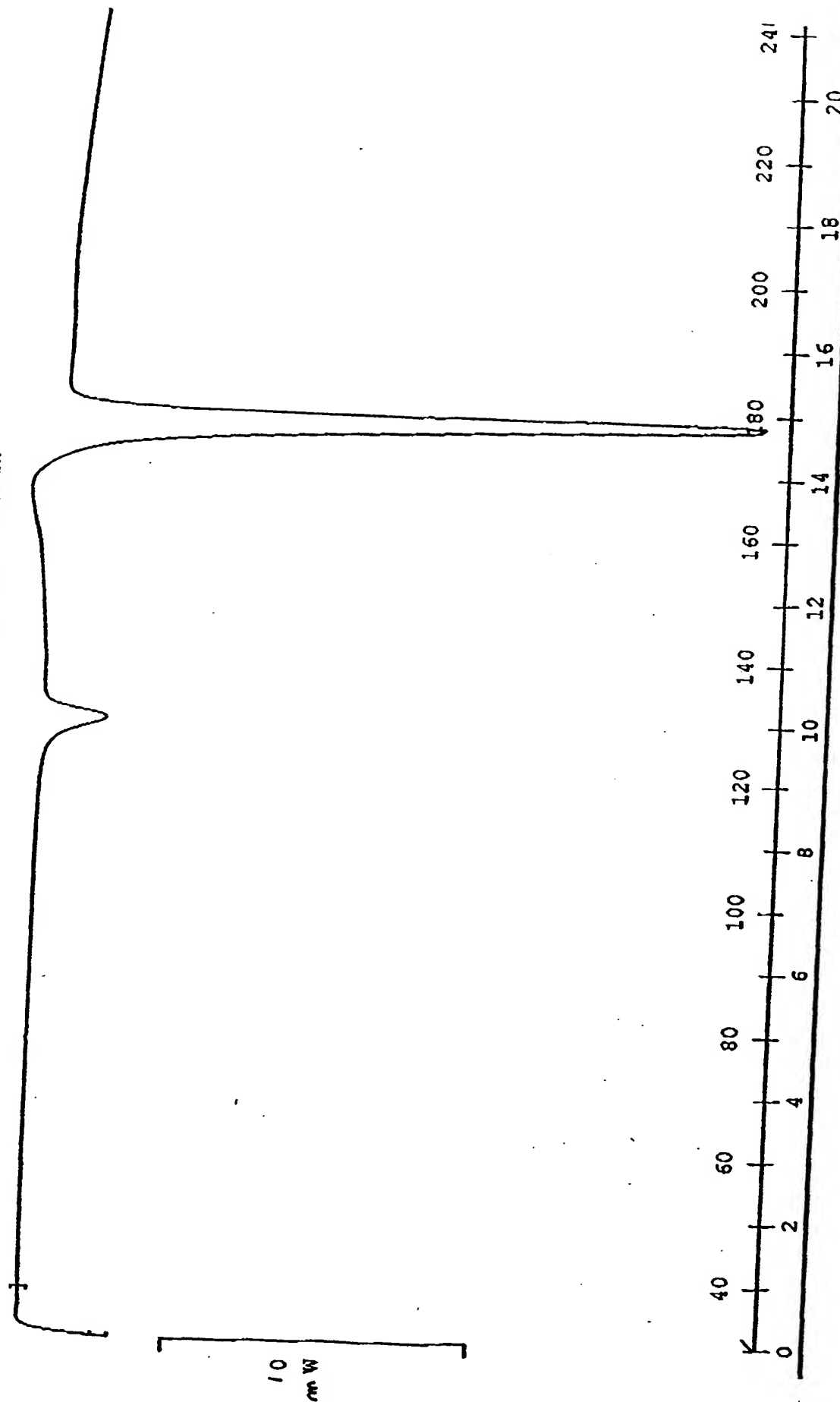


FIGURE 51-56
Form α

IXO

Method: 30-250°C, 10°C/min, 40 ml/min N₂
30.0-250.0°C 10.00°C/min N₂, 40.0 ml/min

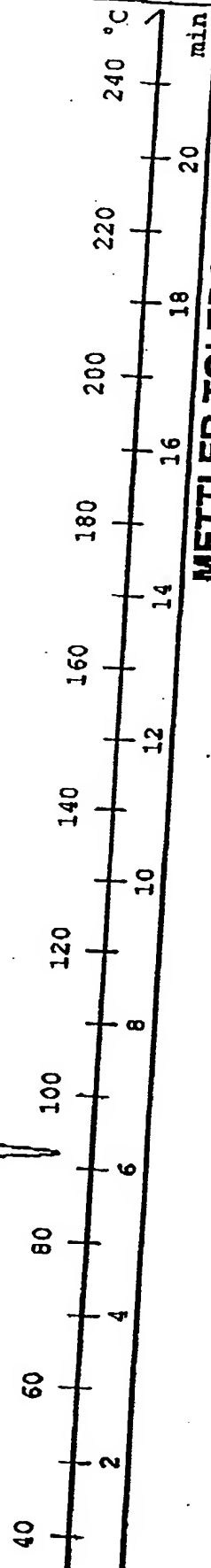


METTLER TOLEDO STAR° SW

FIGURE 57
Form Beta

Method: 30-250°C, 10°C/min, 40 ml/min N₂
30.0-250.0°C 10.00°C/min

N₂, 40.0 ml/min

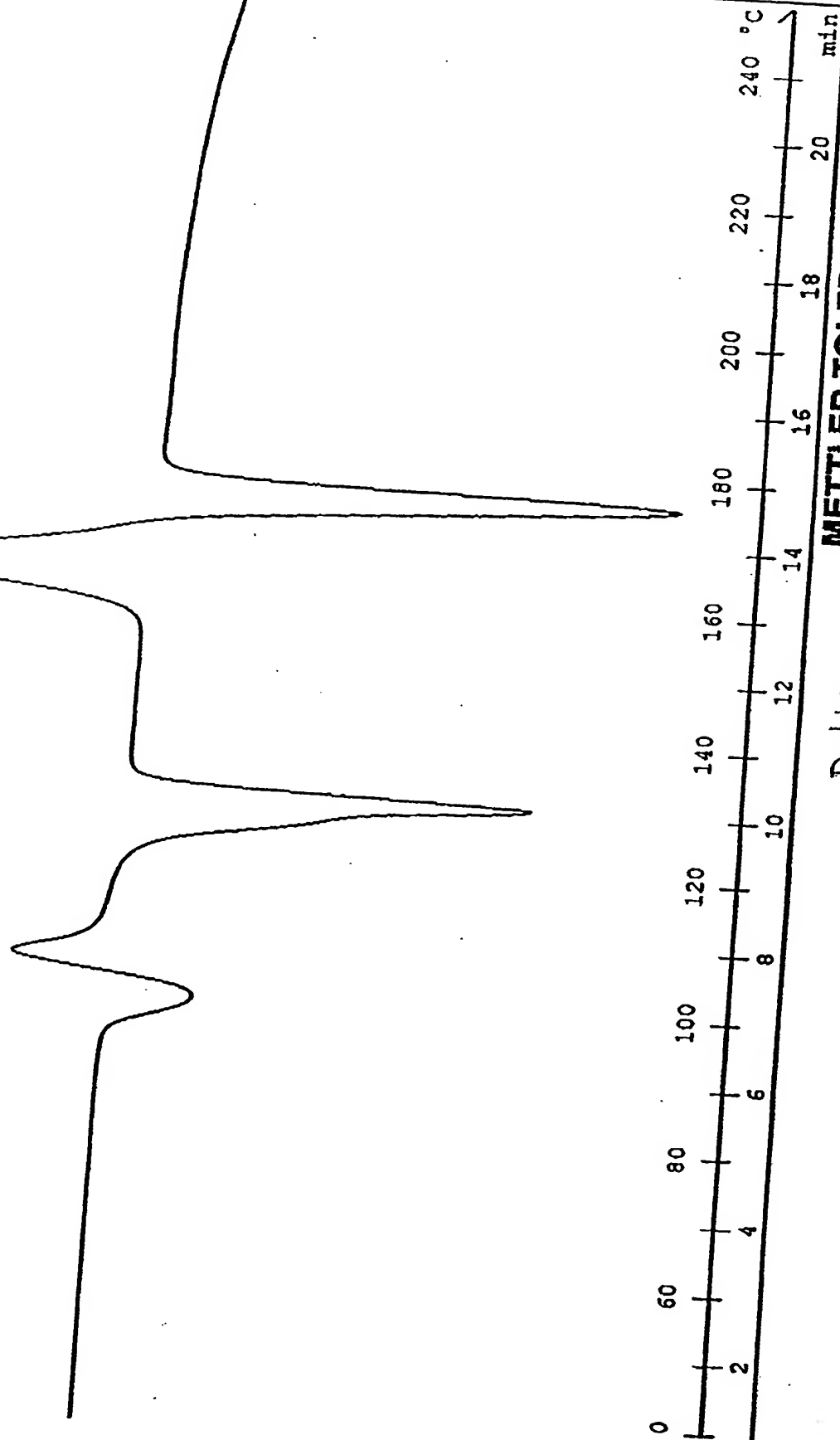


METTLER TOLEDO STAR® System

FIGURE 55-58
Form Delta

Method: 30-250°C, 10°C/min, 40 mL/min N₂
30.0-250.0°C 10.00°C/min

N₂, 40.0 mL/min



METTLER TOLEDO STAR® System

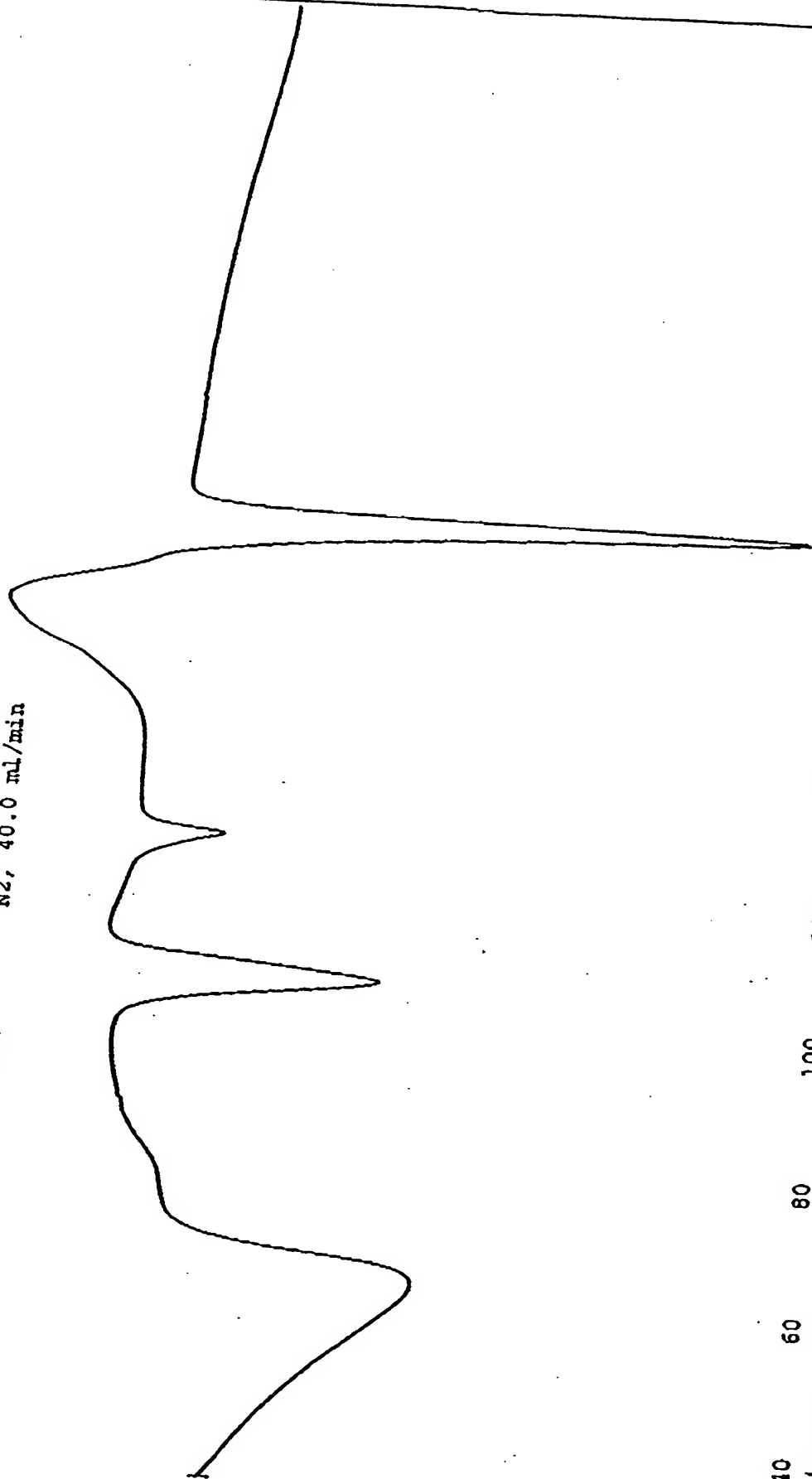
- Delta

Form Epsilon

FIGURE 59

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min

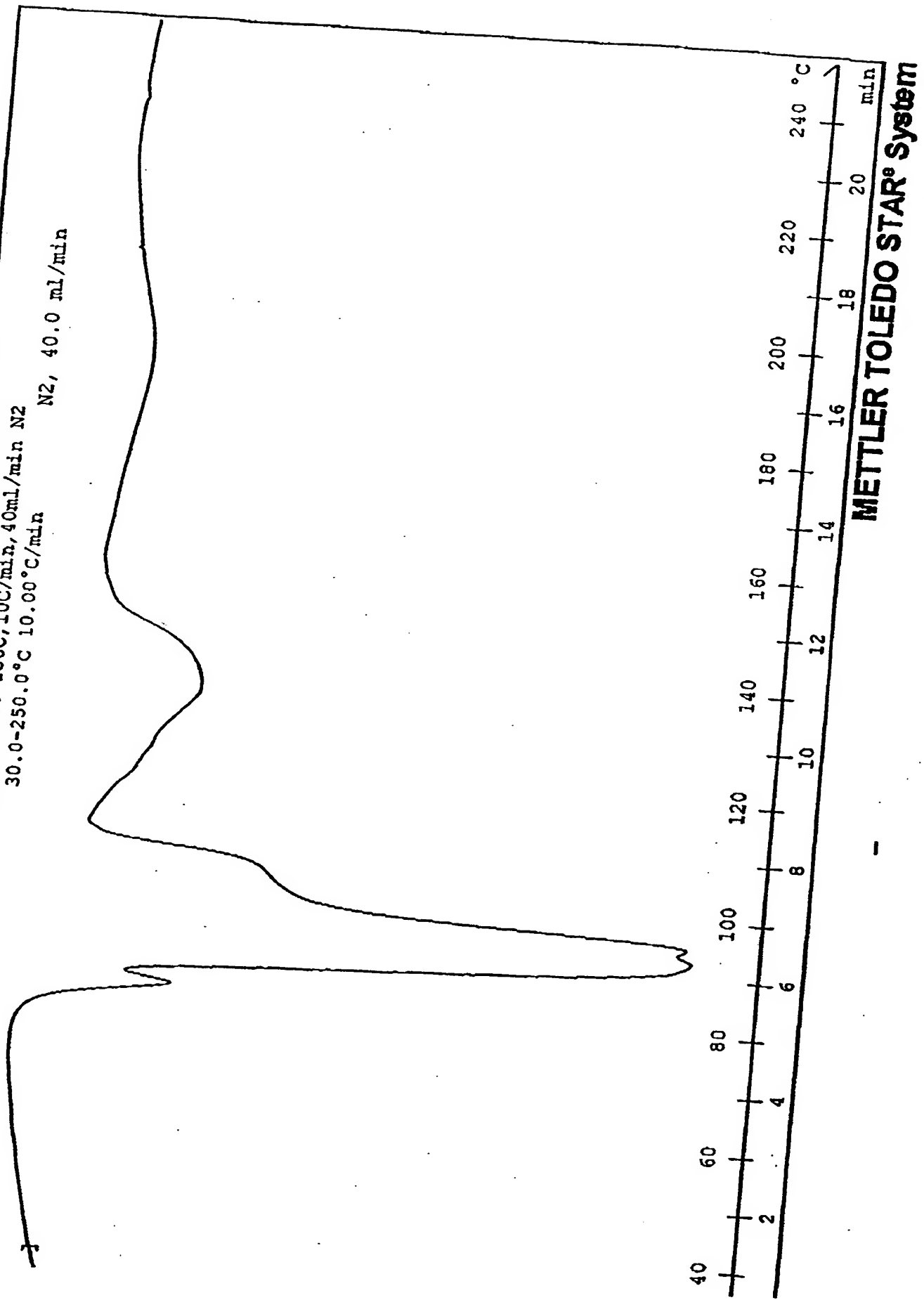


METTLER TOLEDO STAR® System

FIGURE 57
60

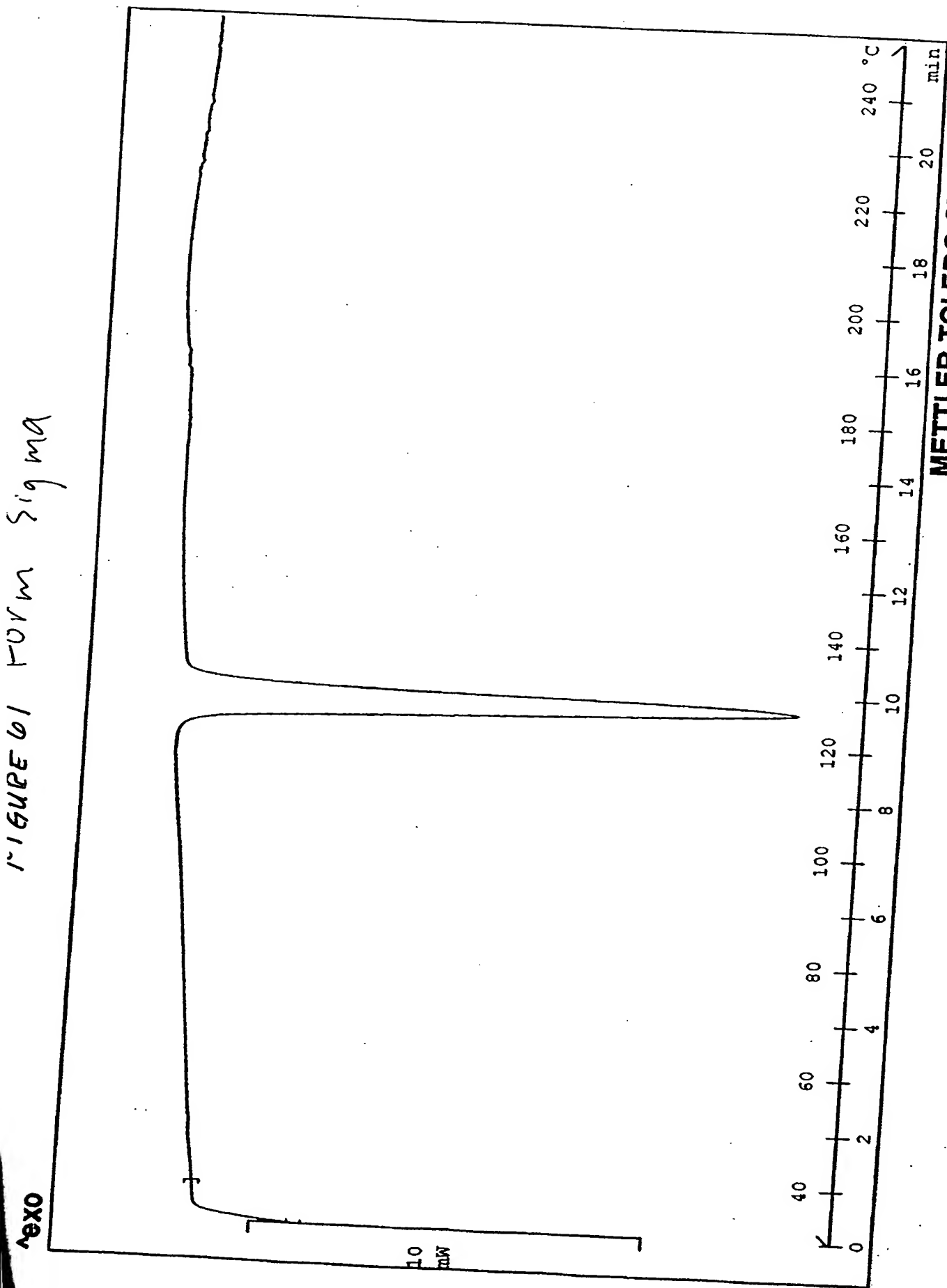
Form ~~P~~ Gamma

Method: 30-250C, 10C/min, 40ml/min N2
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min



METTLER TOLEDO STAR® System

FIGURE 61 Form Sigma

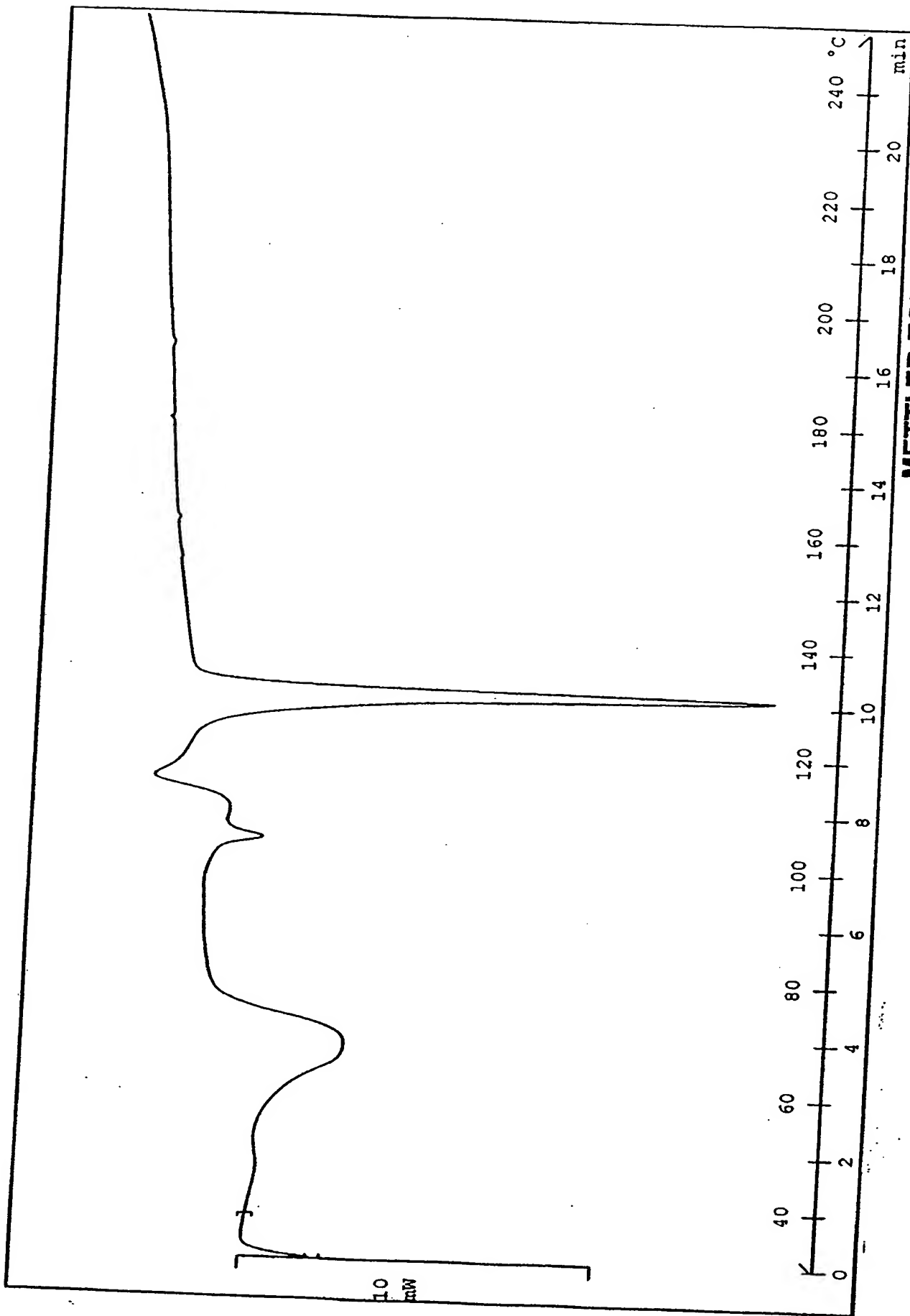


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Form σ (5)

FIGURE 52-62 Form Theta

EXO



METTLER TOLEDO STAR® System

Form 8

Figure 03

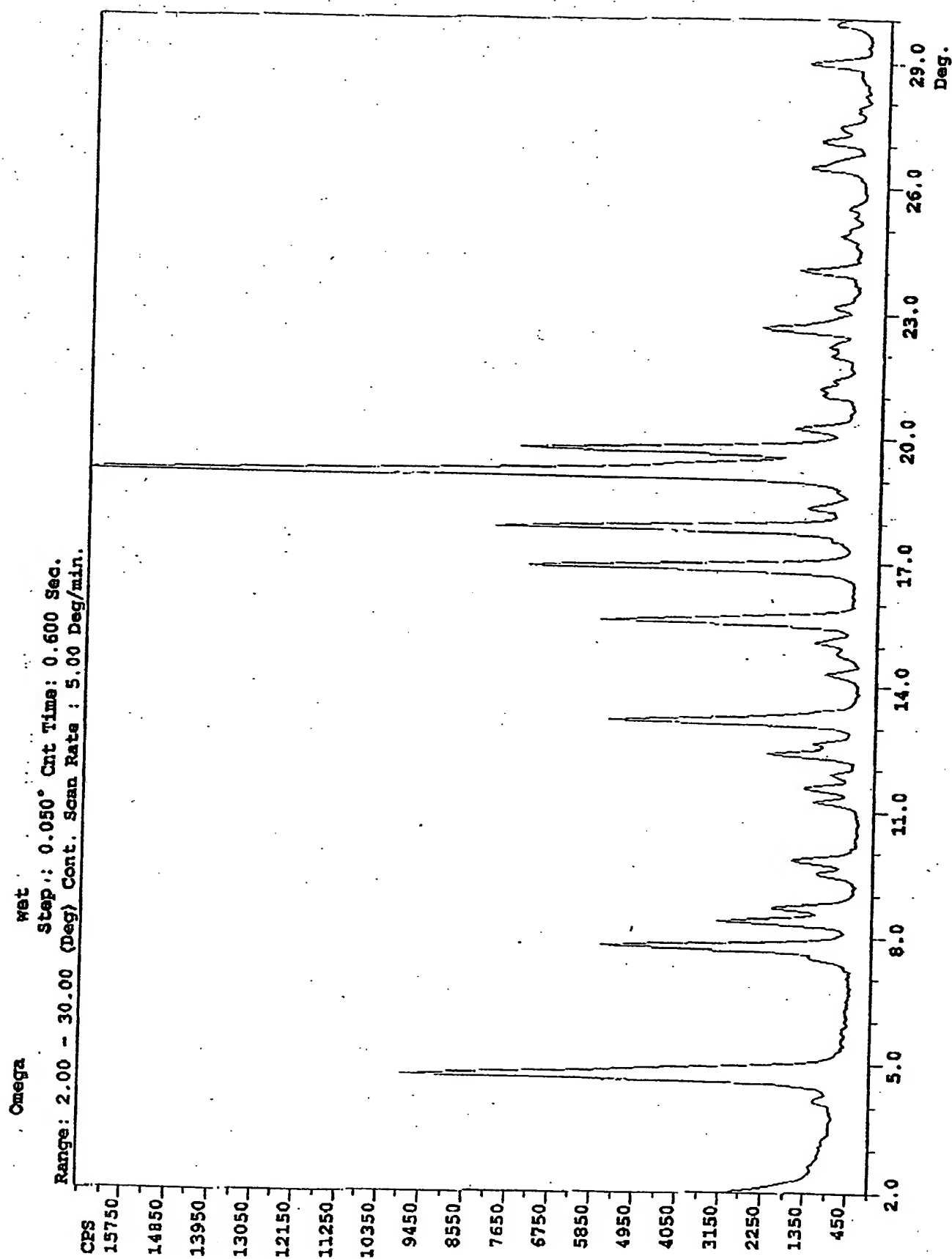


Figure 64

Comparison between the impurity profile of Nateglinide crystallized in IPA-H₂O and Nateglinide crystallized in Methanol-H₂O

Sample No	Solvent	Impurity profile by RRT [% w/w]						
		D-PA (0.23)	(0.25)	(0.46)	(0.80)	Ipcha (0.89)	Dimer (1.38)	Methyl Ester (1.51)
RL-2155/1	Methanol-H ₂ O	<0.01		0.02	<0.01	0.03	0.02	2.91
RL-2163/4	IPA-H ₂ O	<0.01	0.04		0.02	0.02	0.01	
								0.04
								0.03
								0.02

Note: D-PA means D-Phenyl Alanine

Ipcha means Iso propyl cyclohexyl carboxylic acid

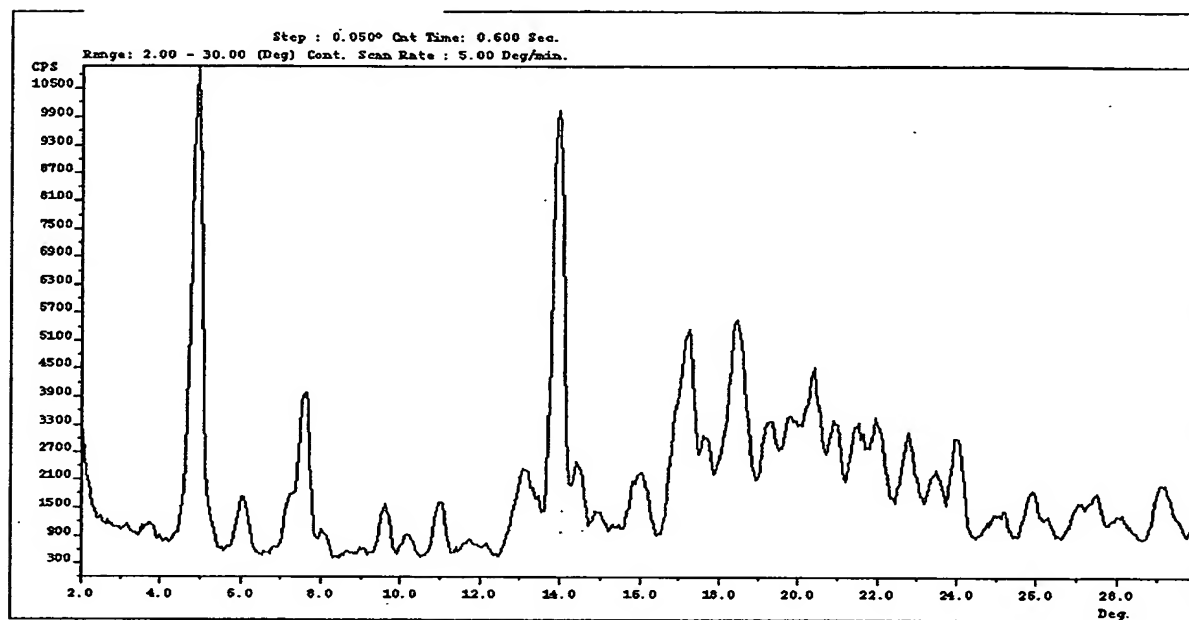
Both are the starting materials of the product

(-)-N-[(trans-4-isopropyl cyclohexane)carbonyl]-D-phenylalanine

Newly Added

Figure 65

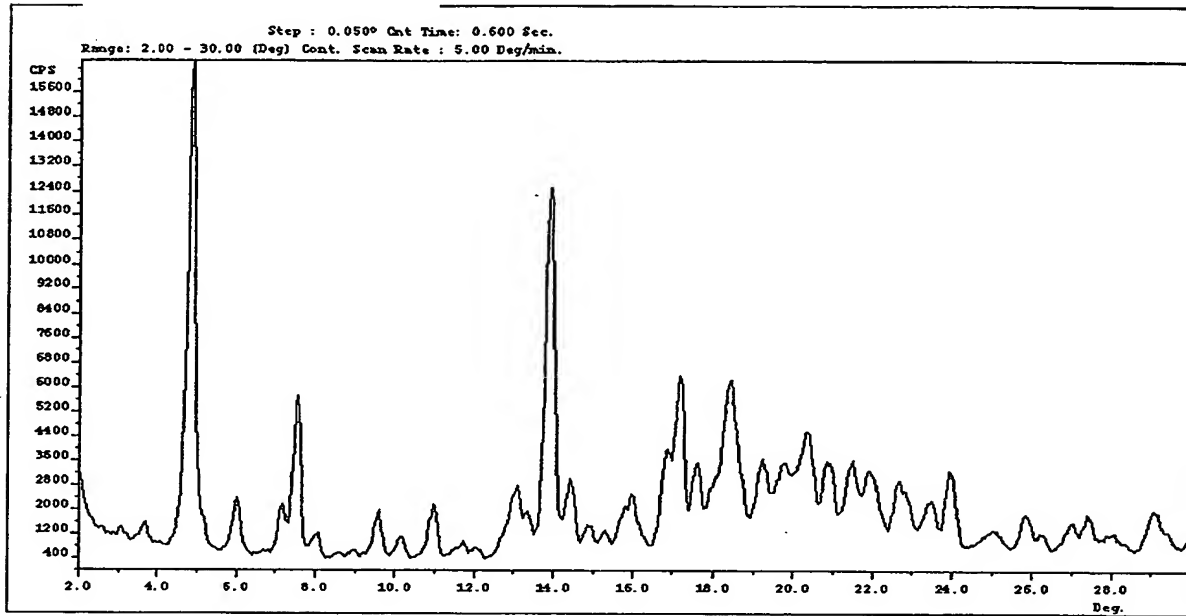
Form U- Crystallization in Ethyl-Acetate – drying at 30°C- Sample prepared according to Example 17,



Newly Added.

Figure 66

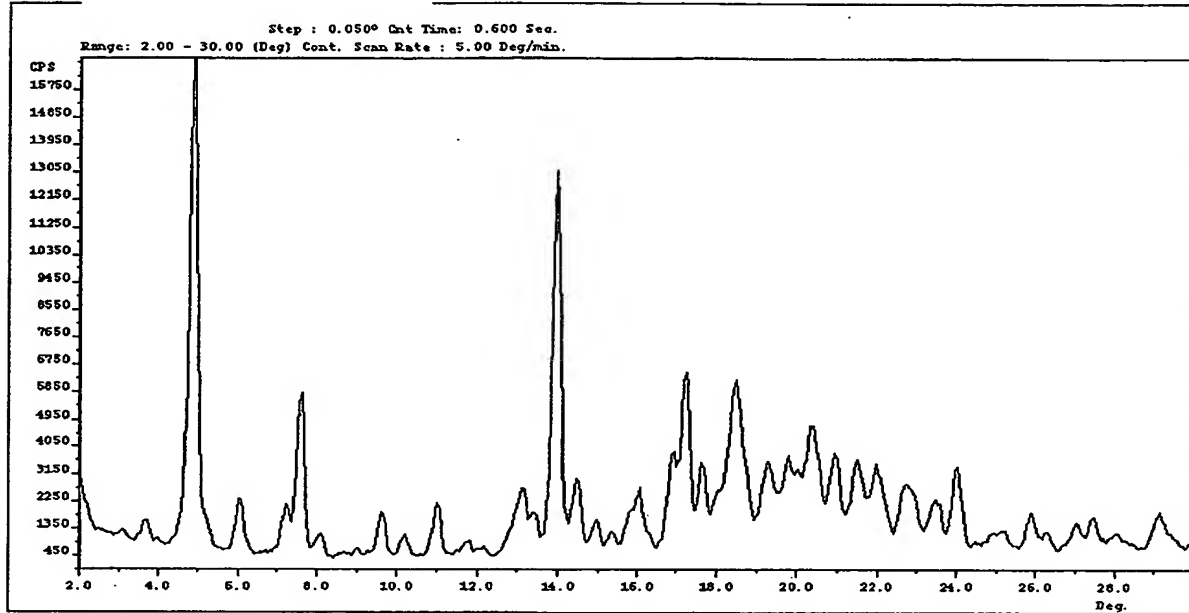
Form U- Crystallization in Ethyl-Acetate – drying at 50°C - Sample prepared according to Example 17.



Newly Added.

Figure 67

Form U- Crystallization in Ethyl-Acetate – drying at 90°C - Sample prepared according to Example 17.



Newly Added.

Figure 68

Form U- Crystallization in Acetone - Sample prepared according to Example 17.

